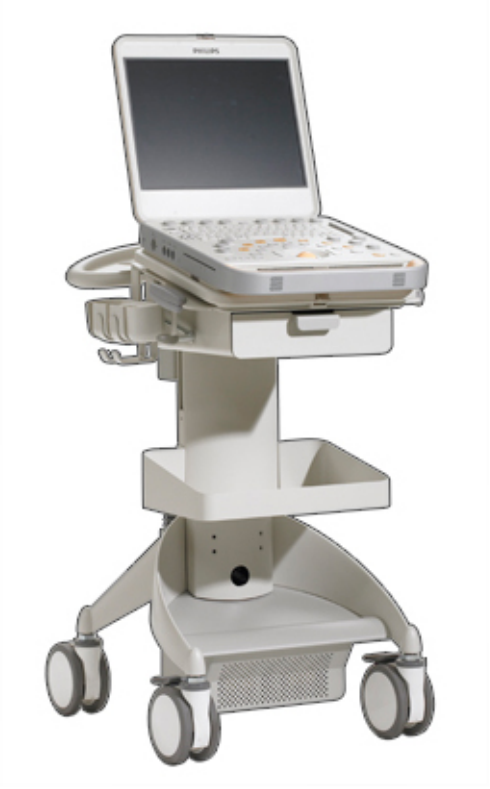
CX50 Ultrasound System

User Manual

4535 613 06532 Rev A
September 2008



PHILIPS

Manufactured by Philips Ultrasound

22100 Bothell-Everett Highway
Bothell, WA 98021-8431
USA
Telephone: +1 425-487-7000 or 800-426-2670
Fax: +1 425-485-6080
www.philips.com/ultrasound

CE 0086

This Medical Device meets the provisions of the transposition of the Medical Device Directive 93/42/EEC within the country of origin of the Notified Body concerned with the device.

European Union Representative

Philips Medical Systems Nederland B.V., a Philips Healthcare Company
PMS Quality and Regulatory Affairs Europe
Veenpluis 4-6
5684 PC Best
The Netherlands

CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

Contents

1 Read This First

This section contains important information about the user information for your system and about contacting Philips Ultrasound.

Intended Audience

Before you use your user information, you need to be familiar with ultrasound techniques. Sonography training and clinical procedures are not included here.

Before you use your QLAB user information, you need to be familiar with diagnostic techniques. Sonography training and clinical procedures are not included here.

This manual is intended for sonographers, physicians, and biomedical engineers who operate and maintain your Philips Ultrasound product.

Warnings

Before using the system, read these warnings and the "Safety" section.

WARNINGS

- Do not remove system covers; hazardous voltages are present inside the system. To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall (wall/mains) outlets.
- Do not operate the system in the presence of flammable anesthetics. Explosion can result.
- Medical equipment needs to be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the "Safety" section.
- The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.

Warning Symbols

The system uses the following warning symbols. For additional symbols used on the system, see the "Safety" section.

Symbol	Description
	Identifies a safety note.
	Dangerous voltages: Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	Indicates that the user should see the instructions for use for safety information.

User Information Components

The user information provided with your Philips Ultrasound product includes the following components:

- ***Compact Disc (CD)***: Includes all of the user information, except the *Operating Notes*. The instructions for using the CD are included with the CD.
- ***Operating Notes***: Contains information that clarifies certain product responses that might be misunderstood or cause user difficulty.
- ***User Manual***: Provided with the product and included on the CD. The *User Manual* introduces you to features and concepts, helps you set up your system, and includes important safety information. This manual also includes

procedures for basic operation. For detailed operating instructions, see the Help.

- ***Help***: Available on the system in some languages and included on the CD, the Help contains comprehensive instructions for using the system. The Help also provides reference information and descriptions of all controls and display elements. To display the Help, press **Help** on the system keyboard.
- ***QLAB Help***: Available on the product in some languages, the *QLAB Help* contains comprehensive instructions for use. It also provides descriptions of all controls and display elements. To display the Help, press **Help** on the system keyboard, or click **?**.
- ***Acoustic Output Tables***: Included on the CD, it contains information about acoustic output and patient-applied part temperatures.
- ***Medical Ultrasound Safety***: Included on the CD, it contains information on bioeffects and biophysics, prudent use, and implementing ALARA (as low as reasonably achievable).
- ***Shared Roles for System and Data Security***: Contains guidelines to help you understand how the security of your ultrasound system could be compromised and information on Philips efforts to help you prevent security breaches.

Product Conventions

Your Philips product uses certain conventions throughout the interface to make it easy for you to learn and use:

- Two unlabeled buttons are used with the trackball. Those controls, located on either side of the trackball, operate somewhat similarly to PC mouse buttons.
- Tabs along the top of the monitor display let you choose additional sets of setup options.
- To type text into a text field, click in the field and use the keyboard.
- To display a list, click the down arrow  . To scroll through a list, click the arrows at either end of the scroll bar or drag the scroll box up or down.

- Controls on the control panel include buttons, knobs, slide controls, and a trackball. Press a button to activate or deactivate its function. Turn a knob to change the selected setting. Move a slide control to change its setting. Roll the trackball in the direction that you want to move a caliper or object.
- Controls across the top of the control panel, called quick keys, function as both buttons and knobs. To select one of the functions displayed above the control, simply press the control. To select a setting for the function, also displayed above the control, turn the control.

User Information Conventions

The user information for your Philips product uses the following typographical conventions to assist you in finding and understanding information:

- Hypertext links appear in blue.
- All procedures are numbered, and all subprocedures are lettered. You must complete steps in the sequence they are presented to ensure success.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text. The only exceptions are the trackball and the buttons adjacent to it, which are unlabeled.
- Symbols appear as they appear on the system.
- *Point* means to position the tip of the pointer or cursor on an item on the display.
- *Click* means to move the pointer to an object and press the left trackball button.
- *Select* means to click a check box to put a check mark in it. *Deselect* means clicking the check box to remove the check mark.
- *Double-click* means to quickly click twice to select an object or text.
- *Right-click* means to point at an item and then press and immediately release the right trackball button.
- *Hover* means to pause the pointer over an item on the display.

- *Drag* means to place the pointer over an object and then press and hold the left trackball button while moving the trackball. Use this method to move an object on the display.
- *Highlight* means to change the color of a display selection (such as an item in a list) or overlay it with a colored bar, usually by clicking.
- The left side of the system is to your left as you stand in front of the system, facing the system. The front of the system is nearest to you as you operate it.
- Transducers and pencil probes both are referred to as transducers, unless the distinction is important to the meaning of the text.

QLAB Help topics may contain information that is different for the PC and ultrasound editions of the QLAB software. Where this occurs, the information common to both editions is presented first, followed by the PC-specific information, and then the ultrasound-specific information.

Information that is essential for the safe and effective use of your Philips product appears throughout your user information as follows:

WARNING

Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract.

NOTE

Notes bring your attention to important information that will help you operate the product more effectively.

Upgrades and Updates

Philips Ultrasound is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated user information will accompany those upgrades.

Customer Comments

If you have questions about the user information, or you discover an error in the user information, in the USA, please call Philips Ultrasound Customer Service at 800-722-9377; outside the USA, please call your local customer service representative. You can also send e-mail to Philips Ultrasound Technical Communications at the following address:

bothell.techpubs@philips.com

Supplies and Accessories

To order additional system batteries for your CX50 system, contact your Philips representative.

To order ECG trunk cables, lead sets, and electrodes; transducer covers; biopsy guides; and other supplies and accessories, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247-9589

Telephone: 800-445-6741 (USA and Canada), +1 319-656-4447 (International)

Fax: 877-329-2482 (USA and Canada), +1 319-656-4451 (International)

E-mail: info@civco.com

Internet: www.civco.com

NOTE

Model or part numbers in the following tables are subject to change.

System Accessories

Accessory	Model/Part Number	Description
ECG cable lead set (AAMI)	453561365771	ECG three-lead cable lead set (AAMI)
ECG cable lead set (IEC)	453561365781	ECG three-lead cable lead set (IEC)
ECG electrode	40420A	Pre-gelled snap electrode
Tip guards	610-748	Transducer tip protector for most TEE transducers
	667-094	Transducer tip protector for X7-2t transducers
Bite guard	M2203A	Bite guard for TEE transducers
Transducer covers	610-680	Protective sheath for TEE transducers
	610-833	Covers for noninvasive or noncavity transducers
Cables		See "Approved Cables for Electromagnetic Compliance" on page 62
Printers	–	See "External Printers" on page 90
Transducers	–	See "Clinical Options and Transducers" on page 170
Removable media	–	See "Media Compatibility" on page 142

Customer Service

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips

Ultrasound representative for assistance. You can also contact one of the following offices for referral to a customer service representative, or visit the Philips Ultrasound Web site:

www.philips.com/ultrasound

Corporate and North American Headquarters

22100 Bothell-Everett Highway, Bothell, WA 98021-8431, USA

800-722-9377

Asia Pacific Headquarters

Level 9, Three Pacific Place, 1 Queen's Road East, Wanchai, Hong Kong

+852 2821 5888

European Headquarters (also serves Africa and the Middle East)

Philips Medizin Systeme Böblingen GmbH

Hewlett-Packard-Str. 2, 71034 Böblingen, Germany

+49 40 5078 4532

Latin American Headquarters

1550 Sawgrass Corporate Parkway, Suite 300, Sunrise, FL 33323, USA

+1 954-628-1000

WEEE Recycling Information

The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) requires producers of electrical and electronic equipment to provide reuse and treatment information for each product. This information identifies, for reuse centers and treatment and recycling facilities, the electrical and electronic components and materials and the location of dangerous substances and preparations in the equipment. Such "recycling passports" for Philips Ultrasound systems are available on this Web site:

www.medical.philips.com/main/company/sustainability/recycling/ultrasound/

2 Safety

Please read this information before using your ultrasound system. It applies to the ultrasound system, transducers, recording devices, and any optional equipment. This section covers general safety information only. Safety information that applies only to a specific task is included in the procedure for that task.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

A WARNING describes precautions necessary to prevent injury or loss of life.

A CAUTION describes precautions necessary to protect the equipment.

Electrical Safety

This equipment has been verified by a recognized third-party testing agency as a Class I device with Type BF and Type CF isolated patient-applied parts, and Type B non-isolated patient-applied parts. (The safety standards met by this system are included in the "Specifications" section of the Help.) For maximum safety observe these warnings and cautions:

WARNINGS

- Shock hazards may exist if this system (when mounted on its cart or plugged directly into an AC power source), including all externally mounted recording and monitoring devices, is not properly grounded. Protection against electrical shock is provided by grounding the cart or the AC power adapter with a three-wire cable and plug, which must be plugged into a grounded outlet. The grounding wire must not be removed or defeated.
- To avoid the risk of electrical shock, never connect the system power cord to a power strip or extension cord. When using the power cord, always connect it directly to a grounded wall outlet.
- Use only the AC adapter supplied with your system.
- Because Type B transducers are not isolated and have a higher inherent leakage current, those transducers are not intended for invasive use.
- Do not remove the protective covers on the system; hazardous voltages are present inside. Cabinet panels must be in place while the system is in use. All internal adjustments and replacements must be made by a qualified Philips Ultrasound field service engineer.
- Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.
- To avoid risk of electrical shock hazards, always inspect the transducer before use: Check the face, housing, and cable before use. Do not use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded.
- To avoid risk of electrical shock hazards, always turn off the system, disconnect it from the wall outlet, and remove the battery (see "Installing the Battery" on page 131) before cleaning the system.
- All patient-contact devices, such as transducers, pencil probes, and ECG leads not specifically indicated as defibrillation-proof must be removed from patient contact before application of a high-voltage defibrillation pulse. See "Defibrillators" on page 25.
- During transesophageal echocardiographic (TEE) procedures, either remove the TEE transducer from the patient or disconnect the TEE transducer from the system immediately following image acquisition.

- Ultrasound equipment in normal operation, as with other medical electronic diagnostic equipment, uses high-frequency electrical signals that can interfere with pacemaker operation. Though the possibility of interference is slight, be alert to this potential hazard and stop system operation immediately if you note interference with a pacemaker.
- When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.
- The system and patient-applied parts meet the standard IEC 60601-1. Applied voltages exceeding the standard, although unlikely, may result in electrical shock to the patient or operator.
- Connection of optional devices not supplied by Philips Ultrasound could result in electrical shock. When such optional devices are connected to your ultrasound system, ensure that the total system earth leakage current does not exceed 500 µA, or in the United States, 300 µA.
- To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See the "Transducer Care" section.
- To avoid risks of electrical shock and fire hazards, inspect the system power cord and plug regularly. Ensure that they are not damaged in any way.
- Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.
- Operating the system with physio input signals that are below the specified minimum levels may cause inaccurate results. See the "Specifications" section in the Help.

- Electrosurgical units (ESUs) and other devices intentionally introduce radio frequency electromagnetic fields or currents into patients. Because imaging ultrasound frequencies are coincidentally in the radio frequency range, ultrasound transducer circuits are susceptible to radio frequency interference. While an ESU is in use, severe noise interferes with the black-and-white image and completely obliterates the color image. Concurrent failures in an ESU or other device and in the outer layer of the TEE transducer shaft can cause electrosurgical currents to return along the transducer conductors. This could burn the patient, and the ultrasound system and the transducer could also be damaged. Be aware that a disposable transducer cover provides no protective electrical insulation at ESU frequencies.
- To avoid risk of a burn hazard, do not use transducers with high-frequency surgical equipment. A burn hazard may result from a defect in the high-frequency surgical neutral electrode connection.
- Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

CAUTIONS

- Although your system has been manufactured in compliance with existing EMI/EMC requirements, use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. When interference is present or intermittent, use caution when continuing to use the system. If interference occurs often, review the environment in which the system is being used, to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can cause emissions. In cases where EMI is causing disturbances, it may be necessary to relocate your system.
- For information on electromagnetic emissions and immunity as it applies to the system, see "Electromagnetic Compatibility" on page 58. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet those conditions may degrade system performance.

Defibrillators

Observe the following warnings when using a transducer when a defibrillation is required.

WARNINGS

- Before defibrillation, always remove the transducer from the patient.
- Before defibrillation, always disconnect the transducer from the system.
- A disposable transducer cover provides no protective electrical insulation against defibrillation.
- A small hole in the outer layer of the transducer opens a conductive path to grounded metal parts of the transducer. The secondary arcing that could occur during defibrillation could cause patient burns. The risk of burns is reduced, but not eliminated, by using an ungrounded defibrillator.

Use defibrillators that do not have grounded patient circuits. To determine whether or not a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Mechanical Safety

A list of precautions related to mechanical safety follows; observe these precautions when using the system:

WARNINGS

- Be aware of the wheels on the system cart, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Use caution when going up or down ramps.
- When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.
- Position external hardcopy devices away from the system. Ensure that they are secure. Do not stack them on the system.
- When positioning the monitor, move it carefully to avoid pinching hands or extremities against other objects, such as a bed rail.
- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.
- If system operation is abnormal after you move or transport the system, contact Philips Ultrasound Customer Service immediately. System components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.
- To avoid injury, Philips recommends against lifting the system cart.

CAUTIONS

- Before moving the system, ensure that the system is secured for transport. On some systems, that may include ensuring that the monitor is latched, to prevent monitor damage during transport.
- Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.
- Do not roll the system over transducer cables or power cables.

Equipment Protection

Follow these precautions to protect your system:

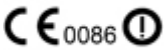
CAUTIONS

- Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system. Do not roll the system over cables, which may damage them.
- Improper cleaning or sterilization of a patient-applied part may cause permanent damage. For cleaning and disinfection instructions, see the "Transducer Care" section.
- Do not submerge the cables of patient-applied parts in solution. The cables are not liquid-tight beyond the applied part/cable or cable/connector interfaces.
- In general, only the area of the transducer acoustic window is liquid-tight. Except where specified in specific transducer-cleaning instructions, do not immerse the remainder of a transducer in any liquid.
- Do not use solvents, such as thinner or benzine, or abrasive cleaners on the system, transducers, or any hardcopy device.
- For optimal performance, connect your ultrasound system to a circuit dedicated solely for the system. Do not connect life-support devices to the same circuit as the ultrasound system.
- If systems, transducers, and peripherals have been in an environment of 10°C (50°F) or below, allow them to reach room temperature before connecting or turning them on. Philips recommends allowing 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage.
- To avoid damaging the flat-panel display in the monitor, do not store the system where the ambient temperature exceeds 65°C (149°F).

Symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. Of those symbols, the following may be used on your ultrasound system and its accessories and packaging.

	Isolated patient connection (Type BF applied part).
	Defibrillation-proof patient connection (Type BF applied part).
	Non-isolated patient connection (Type B applied part).
	Isolated patient connection for applied part intended for intraoperative use, including direct cardiac application and contact with major vessels (Type CF applied part).
	Defibrillation-proof patient connection (Type CF applied part).
	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	Identifies the On/Off control.
	Identifies a safety note.
	Indicates that the user should see the instructions for use for safety information.
	Identifies equipotential ground.

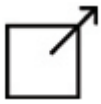
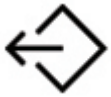
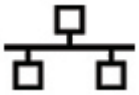
	Identifies earth ground.
	Identifies protective earth ground.
	Nonionizing electromagnetic radiation. Indicates that interference may occur in the vicinity of equipment marked with this symbol.
	The radio component contained in this device is compliant to Council Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive).
	Class 2 radio equipment identifier per Directive 1999/5/EC. European Union member states may apply restrictions on putting this device into service or placing it on the market. This device is intended to be connected to the Publicly Available Interfaces for use throughout the European Economic Area.
IPX0	Indicates that the device is unprotected against fluid ingress.
IPX1	Indicates that the device is protected against the effects of vertically falling water. This degree of protection can apply to transducers.
IPX4	Indicates that the device is protected against the effects of splashing liquids. This degree of protection can apply to foot-operated devices.
IPX7	Indicates that the device is protected against the effects of immersion. This degree of protection can apply to transducers and foot-operated devices.
IPX8	Indicates that the device is protected against the effects of immersion for up to 60 minutes. This degree of protection can apply to foot-operated devices.

	Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by (Pb) or (Hg), components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws. The backlight lamps in an LCD system monitor contain mercury.
	Do not throw away. Dispose of in accordance with local, state, or federal laws.
GMDN	Global Medical Device Nomenclature Code.
	Indicates a possible crushing hazard to hands.
	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	Indicates the temperature range (noncondensing) for transport and storage. (Does not apply to media.)
	Indicates the atmospheric pressure range for transport and storage.
	Indicates the relative humidity range (noncondensing) for transport and storage
	Indicates that a connector receives alternating current.

	Identifies fuse boxes or their locations. For continued protection from fire and shock, replace fuses only with fuses of the same type and rating.
	Identifies the date of manufacture.
	This side up: Points toward the side of the shipping crate that should be kept facing up.
	Indicates that the device should be kept dry.
	Indicates that the device is fragile; handle with care.

The following symbols may also be used on the system and its accessories and packaging:

	Connection for a pencil probe
	Connection for a pencil probe
	Connection for a transducer
	Connection for ECG leads
	Connection for ECG leads

	Print remote output
	Input port for audio left/right, VHS/S-VHS, microphone, CD, or DVD
	Output port for audio left/right, VHS/S-VHS, video patient monitor, black-and-white printer, or interlaced RGB output port
	VGA or parallel output port
	USB input/output port
	Ethernet connection
	System microphone
AUX POWER ISOLATE OUTPUT	Isolated auxiliary power provided for connection of Philips-approved remote accessories
	Foot switch
	Indicates the atmospheric pressure range for transport and storage.

The following symbols may be used inside the system:

	Dangerous voltages: Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	Indicates equipotential ground.

Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system.

A list of precautions related to biological safety follows; observe these precautions when using the system. For more information refer to *Medical Ultrasound Safety* on your user information CD.

WARNINGS

- Do not use the system if an error message on the video display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your customer service representative.
- Do not use a system that exhibits erratic or inconsistent image updating. Discontinuities in the scanning sequence indicate a hardware failure that must be corrected before use.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.
- Use only acoustic standoffs that have been approved by Philips Ultrasound. For information on ordering approved accessories, see "Supplies and Accessories" on page 18.
- Transducer covers may contain natural rubber latex. Those covers may cause allergic reactions in some individuals. See "FDA Medical Alert on Latex" on page 36.
- The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions. See "FDA Medical Alert on Latex" on page 36.
- In contrast studies using a high-MI acoustic field, capillary rupture, due to microbubble expansion within a capillary in an acoustic field, can cause extravasation. References: (1) Skyba, D.M., Price, R.J., Linka, A.Z., Skalak, T.C., Kaul, S. "Direct in vivo visualization of intravascular destruction of microbubbles by ultrasound and its local effects on tissue." *Circulation*, 1998; 98:290-293. (2) van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000;13(4):288-94.
- Preventricular contractions can be caused by the oscillations of microbubbles when a high-MI acoustic field is triggered in the heart at the end of systole. In a very sick patient with certain risk factors, theoretically, this could lead to ventricular fibrillation. Reference: van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." *Journal of the American Society of Echocardiography*, 2000;13(4):288-94.

- If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Heath Organization: WHO/CDS/ APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.
- If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your Philips service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.
- The backlight lamps in the system displays contain mercury and must be recycled or disposed of according to local, state, or federal laws.
- Select the correct application when starting an exam, and remain in that application throughout the exam. Some applications are for parts of the body that require lower limits for acoustic output.
- The CX50 system is not qualified for ophthalmic use.
- When used off the cart, the AC adapter and the system should not be placed on the floor or on a patient's bed. You can place it on a table or chair.

FDA Medical Alert on Latex

March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after

several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA's recommendations to health professionals in regard to this problem are as follows:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.) To report an incident, call the FDA Problem Reporting Program, operated through the U.S. Pharmacopoeia toll-free number: 800-638-6725. (In Maryland, call collect 301-881-0256.)

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

NOTE

The ultrasound system and transducers described in this document do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducer. It also is not used on Philips ECG cables for the products described in this document.

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer's responsibility to control total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, an ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound, not only in the technology but in the applications of that technology, have resulted in the need for more and better information to guide the user. The output display indices are designed to provide that important information.

There are a number of variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include index values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

Applying ALARA

The system imaging mode used depends upon the information needed. 2D and M-mode imaging provide anatomical information, while Doppler, Color Power Angio (CPA), and Color imaging provide information about blood flow. A scanned mode, like 2D or Color, disperses or scatters the ultrasonic energy over an area, while an unscanned mode, like M-mode or Doppler, concentrates ultrasonic energy. Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgment. Additionally, the transducer frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to transducer surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

Acoustic Output Limits

This ultrasound system maintains acoustic output below the appropriate limits for each application, as listed here.

Limits for Non-Ophthalmic Applications

- Ispta (derated) ≤ 720 mW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

WARNING

The CX50 system is not qualified for ophthalmic use.

Direct Controls

Application selection and the output-power control directly affect acoustic intensity. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things that occurs in any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular application, while others require manual selection. Ultimately, the user has the responsibility for proper clinical use. The ultrasound system provides both automatic (default) settings and manual (user-selectable) settings.

Output power has direct impact on acoustic intensity. Once the application has been established, the power control can be used to increase or decrease the intensity output. The power control allows you to select intensity levels less than the established maximum. Prudent use dictates that you select the lowest output intensity that is consistent with good image quality.

Indirect Controls

The indirect controls are those that have an indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency, focus depth, pulse length, and transducer selection.

The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an unscanned mode.

Pulse repetition frequency or rate refers to the number of ultrasound bursts of energy over a specific period of time. The higher the pulse repetition frequency, the more pulses of energy in a period of time. Several controls affect pulse repetition frequency: focal depth, display depth, sample volume depth, flow optimization, scale, number of focal zones, and sector-width controls.

Focus of the ultrasound beam affects the image resolution. To maintain or increase resolution at a different focus requires a variation in output over the focal zone. This variation of output is a function of system optimization. Different exams require different focal depths. Setting the focus at the proper depth improves the resolution of the structure of interest.

Pulse length is the time during which the ultrasonic burst is turned on. The longer the pulse, the greater the time-average intensity value. The greater the time-average intensity, the greater the likelihood of temperature increase and cavitation. Pulse length, burst length, or pulse duration is the output pulse duration in PW Doppler. Increasing the Doppler sample-volume size increases the pulse length.

Transducer selection indirectly affects intensity. Tissue attenuation changes with frequency. The higher the transducer operating frequency, the greater the attenuation of the ultrasonic energy. A higher transducer operating frequency requires more output intensity to scan at a deeper depth. To scan deeper at the same output intensity, a lower transducer frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency transducer is needed.

Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, TGC, dynamic range,

and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example, before increasing output, optimize gain to improve image quality.

An Example of Applying the ALARA Principle

An ultrasound scan of a patient's liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the transducer, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output.

Having localized the blood flow, use the Doppler controls to position the sample volume over the vessel. Before increasing output, adjust velocity range or scale and Doppler gain to obtain an optimal Doppler trace. Only if maximum Doppler gain does not create an acceptable image do you increase output.

In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by using focus, receiver gain, and other imaging controls. If the image is not diagnostically useful at this point, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow-up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it should be used efficiently and effectively.

Output Display

The system output display comprises two basic indices: a mechanical index and a thermal index. The thermal index further consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). One of these three thermal indices will be displayed at all times. Which one depends upon the system preset or user choice, depending upon the application at hand.

The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1 for all applications except contrast, where the minimum increment is 0.01.

The thermal index comprises three indices, and only one of these is displayed at any one time. Each transducer application has a default selection that is appropriate for that combination. The TIB, TIS, or TIC is continuously displayed over the range of 0.0 to maximum output, based on the transducer and application, in increments of 0.1. For the location of the output display, see "Imaging Display" on page 136.

The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state that is preset by the manufacturer or the operator. The system has default index settings for the transducer application. The default settings are invoked automatically by the ultrasound system when power is turned on, when new patient data is entered into the system data base, or when an application change occurs.

The decision as to which of the three thermal indices to display should be based on the following criteria:

- Appropriate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface, as in a cranial exam.
- Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?

- Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.
- Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

Mechanical Index (MI) Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is actually occurring. The MI should be used as a guide for implementing the ALARA principle.

Thermal Index (TI) Displays

The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone.

The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone.

The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue.

You can choose to display TIS, TIC, or TIB. (For details on changing the TI display, see the system Help.) On systems with transcranial applications, TIC is displayed when you select a transcranial preset.

Mechanical and Thermal Indices Display Precision and Accuracy

The MI and TI precision is 0.1 unit on the system.

The MI and TI display accuracy estimates for the system are given in *Acoustic Output Tables*, on your user information CD. Those accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability, as discussed in this section.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the American Institute of Ultrasound in Medicine (AIUM) measurement standard. The measurements are then put into algorithms for calculating the displayed output values.

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Overestimation of actual *in situ* intensity exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example:

- The measured water tank values are derated using a conservative, industry standard, attenuation coefficient of 0.3 dB/cm-MHz.
- Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.
- Steady State temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound transducer is held steady in one position long enough for steady state to be reached.

A number of factors are considered when estimating the accuracy of the displayed values: hardware variations, estimation algorithm accuracy, and measurement

variability. Variability among transducers and systems is a significant factor. Transducer variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations. Differences in system pulser voltage control and efficiencies is also a contributor to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3 dB/cm-MHz attenuative medium is not considered in the accuracy estimate for the display. Neither linear propagation, nor uniform attenuation at the 0.3 dB/cm-MHz rate, occur in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and in particular, in water tank measurements, nonlinear propagation and saturation losses occur as pulser voltages increase.

Therefore, the display accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the AIUM measurement standards, or the effects of nonlinear loss on the measured values.

Control Effects

Controls Affecting the Indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the output power control is adjusted; but other system controls affect the on-screen output values.

Power

The output power control affects the system acoustic output. Two real-time output values are on the display: a TI and MI. They change as the system responds to power-control adjustments.

In combined modes, such as simultaneous Color, 2D, and PW Doppler, the individual modes each add to the total TI. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest MI.

2D Controls

- **Sector Width:** Narrowing the sector angle may increase frame rate. This action will increase the TI. Pulser voltage may be automatically adjusted down with software controls to keep the TI below the system maximums. A decrease in pulser voltage will decrease MI.
- **Zoom:** Increasing the zoom magnification by pressing **Zoom** may increase frame rate. This action will increase the TI. The number of focal zones may also increase automatically to improve resolution. This action may change the MI, because the MI can occur at a different depth.
- **Number of Focal Zones:** More focal zones may change both the TI and MI by changing frame rate or focal depth automatically. Lower frame rates decrease the TI. MI displayed will correspond to the zone with the largest MI.
- **Focus:** Changing the focal depth will change MI. Generally, higher MI values will occur when the focal depth is near the natural focus of the transducer.

Color and Power Controls

- **Color Optimization:** Increasing the color sensitivity with the color optimization control may increase the TI. More time is spent scanning the color image. Color pulses are the dominant pulse type in this mode.
- **Color Sector Width:** Narrower color sector width will increase color frame rate and the TI will increase. The system may automatically decrease pulser voltage to stay below the system maximum. A decrease in pulser voltage

will decrease the MI. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.

- **Color Sector Depth:** Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the MI of the dominant pulse type which is a color pulse. However, if PW Doppler is also enabled then PW Doppler will remain the dominant mode and the TI change will be small.
- **Scale:** Using the scale control to increase the color velocity range may increase the TI. The system may automatically adjust pulser voltage to stay below the system maximums. A decrease in pulser voltage will also decrease MI.
- **Sector Width:** A narrower 2D sector width in Color imaging will increase color frame rate. The TI will increase. MI will not change. If PW Doppler is also enabled, then PW Doppler will remain the dominant mode and the TI change will be small.

M-Mode and Doppler Controls

- **Simultaneous and Update Methods:** Use of combination modes affects both the TI and MI through the combination of pulse types. During simultaneous mode, the TI is additive. During duplex, the TI will display the dominant pulse type. The displayed MI will be from the mode with the largest MI value.
- **Sample Volume Depth:** When Doppler sample volume depth is increased, the Doppler PRF may automatically decrease. An increase in PRF will increase the TI. The system may also automatically decrease the pulser voltage to remain below the system maximum. A decrease in pulser voltage will decrease MI.

Other Control Effects

- **Imaging Mode Controls:** When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or

simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

- **Transducer:** Each transducer type has unique specifications for contact area, beam shape, and center frequency. Defaults are initialized when you select a transducer. Factory defaults vary with transducer, application, and selected mode. Defaults have been chosen below the FDA limits for intended use.
- **2D Depth:** An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease the TI. The system may also automatically choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.
- **Application:** Acoustic output defaults are set when you select an application. Factory defaults vary with transducer, application, and mode. Defaults have been chosen below the FDA limits for intended use.

Related Guidance Documents

For more information about ultrasonic bioeffects and related topics, see the following:

- "Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.
- "American Institute of Ultrasound in Medicine Bioeffects Consensus Report." *Journal of Ultrasound in Medicine*, Vol. 27, Issue 4, April 2008.
- Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- Second Edition of the AIUM Output Display Standard Brochure, Dated March 10, 1994. (A copy of this document is provided with each system.)
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. FDA, September 1997.
- Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- WFUMB. "Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological

Effects of Ultrasound." *Ultrasound in Medicine and Biology*, 1998: Vol. 24, Supplement 1.

Acoustic Output and Measurement

Since the initial use of diagnostic ultrasound, the possible human bioeffects from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee ("Bioeffects Considerations for the Safety of Diagnostic Ultrasound." *Journal of Ultrasound in Medicine*, Vol. 7, No. 9 Supplement, September 1988), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report, "Bioeffects and Safety of Diagnostic Ultrasound," dated January 28, 1993, provides more-current information.

The acoustic output for this system has been measured and calculated in accordance with the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (Revision 3, AIUM, NEMA, 2004), the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (Revision 2, AIUM, NEMA, 2004), and the September, 1997, FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water absorbs very little acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, *In Situ*, has been estimated by using the following formula:

$$In\ Situ = Water\ [e^{-0.23alf}]$$

Where:

In Situ = *In Situ* intensity value

Water = Water value intensity

e = 2.7183

a = Attenuation factor

Tissue = a(dB/cm-MHz)

Amniotic Fluid = 0.006

Brain = 0.53

Heart = 0.66

Kidney = 0.79

Liver = 0.43

Muscle = 0.55

l = Skin line to measurement depth (cm)

f = Center frequency of the transducer/system/mode combination (MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *in situ* intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the *In Situ* value which is commonly reported uses the formula:

$$In\ Situ\ derated = Water\ [e^{-0.069lf}]$$

Since this value is not the true *in situ* intensity, the term "derated" is used.

Mathematical derating of water based measurements using the 0.3 dB/cm-MHz coefficient, may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/cm-MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and

derated values may not be related by the *in situ* (derated) formula. For example: A multi-zone array transducer that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models and Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels *in situ* from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm-MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *in situ* acoustic exposure when the path between the transducer and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cm-MHz. When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned transabdominally, this model may underestimate the *in situ* acoustical exposure. The amount of underestimation depends on each specific situation. For example, when the beam path is longer than 3 cm and the propagation medium is predominantly fluid (conditions that may exist during transabdominal OB scans), a more accurate value for the derating term is 0.1 dB/cm-MHz.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *in situ* acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/MHz may be used during all trimesters.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded mechanical index (MI) values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D, M-mode, PW Doppler, and Color flow imaging.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 PW Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C for first-trimester fetal tissue and 7°C for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a "fixed-path" tissue model and are for devices having Ispta (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28, 1993).

Acoustic Output Tables

Acoustic output tables are in *Acoustic Output Tables*, on your user information CD.

Acoustic Measurement Precision and Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

NOTE

Per Section 6.4 of the Output Display Standard, measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

Acoustic Measurement Precision

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rarefactional pressure measured in MPa.	Pr: 5.4%
Wo is the ultrasonic power in mW.	6.2%
f_c is the center frequency in MHz (NEMA UD-2 definition).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in J/cm^2.	P11.3: 3.2%

Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in MegaPascals.	Pr: ±11.3%
Wo is the ultrasonic power in milliWatts.	±10%
f_c is the center frequency in MHz (NEMA UD-2 definition).	±4.7%
PII.3 is the derated spatial-peak pulse intensity integral in Joules/cm^2.	PII.3: +18% to -23%

Operator Safety

The following issues and situations can affect operator safety when you are using an ultrasound system.

Repetitive Strain Injury

Repetitive ultrasound scanning has been associated with carpal tunnel syndrome (CTS) and related musculoskeletal problems. Some investigators have looked at a large population of sonographers with different types of equipment. An article, with feedback from a smaller geographical area, makes the following recommendations:

- Maintain your joints in optimum positions with a balanced posture while scanning.
- Allow frequent breaks to give soft tissue a chance to recuperate from awkward positions and repetitive movement.
- Avoid gripping the transducer with excessive force.

Repetitive Strain References

Pike, I., et al. "Prevalence of Musculoskeletal Disorders and Related Work and Personal Factors Among Diagnostic Medical Sonographers." *Journal of Diagnostic Medical Sonographers*, Vol. 13, No. 5: 219-227, September 1997.

Necas, M. "Musculoskeletal Symptomatology and Repetitive Strain Injuries in Diagnostic Medical Sonographer." *Journal of Diagnostic Medical Sonographers*, 266-227, November/December 1996.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. See "Clinical Options and Transducers" on page 170 for a list of the transducers that are compatible with your ultrasound system.

Glutaraldehyde Exposure

The United States Occupational Safety and Health Administration (OSHA) has issued a regulation covering levels of acceptable glutaraldehyde exposure in the working environment. Philips does not sell glutaraldehyde-based disinfectants with its products, but this type of disinfectant is recommended for the disinfection of transducers used in TEE, intraoperative, endocavity, and biopsy procedures.

To reduce the presence of glutaraldehyde fumes in the air, be sure to use a covered or ventilated soaking basin. Such systems are commercially available. The most-current information about disinfection products and Philips transducers can be found on the Philips Transducer Care Web site:

www.healthcare.philips.com/us/products/ultrasound/transducers/transducercare/

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection-control procedures established in your clinic or hospital for the protection of both the staff and the patient.

Handling Contaminated Transducers

The primary area of concern is the handling of transducers that have contacted infected patients. Always wear gloves when you handle transducers used in TEE, endocavity, intraoperative, and biopsy procedures that have not been previously disinfected.

For information on cleaning and disinfecting transducers, see the "Transducer Care" section.

Removing Blood and Infectious Material from the System

CAUTION

Do not wipe the transducer housing joint, strain relief, or cable with isopropyl alcohol. Isopropyl alcohol can damage these parts of the transducer. This damage is not covered by the warranty or your service contract. Also, do not use isopropyl alcohol on TEE transducers (except for their handles).

Use a gauze pad moistened with soap and water to remove blood on the system and the transducer connectors and cables. Then dry the equipment with a soft cloth to prevent corrosion. You can use a 70% solution of isopropyl alcohol on the system and only on certain parts of some transducers. Additional cleaning agents are available for transducers. For more information, see the "Transducer Care" section.

For more information about removing blood and other infectious material from the system, "Disinfecting System Surfaces" on page 239.

ECG Cables and Lead Sets

For information on cleaning ECG cables and lead sets, "Cleaning the System and ECG Equipment" on page 237.

Disposable Drape

If you believe contamination of the ultrasound system might occur during an exam, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

CAUTION

Position the disposable drape so that it does not block the vents on the ultrasound system, the monitors, or the peripherals.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is defined as the ability of a product, a device, or a system to function satisfactorily in the presence of the electromagnetic phenomena that exists in the location of the product, the device, or the system being used; and, in addition, to not introduce intolerable electromagnetic disturbances to anything in that same environment.

Electromagnetic immunity is the ability of a product, a device, or a system to function satisfactorily in the presence of electromagnetic interference (EMI).

Electromagnetic emissions is the ability of a product, a device, or a system to introduce intolerable electromagnetic disturbances into the use environment.

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. Use of this system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. If this occurs often, review the environment in which the system is being used to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room, or from portable and mobile RF communications equipment such as cellular phones and pagers, or from the existence of radio, TV, or microwave transmission equipment located nearby. In cases where electromagnetic interference (EMI) is causing disturbances, it may be necessary to relocate your system.

The system complies with International Standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard allows the system to be used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

WARNING

Using cables, transducers, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.

CAUTION

Medical equipment has special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the system's accompanying documents.

This section includes information on electromagnetic emissions and immunity as it applies to the system. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet these conditions may degrade system performance.

The information and warnings contained in this and other sections should be observed when installing and using the system to ensure its EMC.

NOTE

See the other electrical-safety warnings and cautions in this section.

If the system is operated within the electromagnetic environment described in "Electromagnetic Immunity" on page 64, the system will remain safe and will provide the following essential performance:

- Imaging
- Doppler audio and spectral display
- Measurements
- Acoustic output
- ECG triggering
- Printing using system printers
- Patient information
- Date and time information

Radio-Frequency Emissions

The following information applies to the system and any radio-frequency device included in or with the system. For information on related labeling, see "Symbols" on page 28.

FCC and Industry Canada Radio Compliance: This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips may cause harmful radio frequency interference and void your authority to operate this equipment.

The 3Com identifier for the radio component in this device is 3CRUSB20075.

The wireless technology radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. This product is intended to be connected to the Publicly Available Interfaces and used throughout the European Economic Area.

ECG Signal

WARNING

Operation of your system with ECG signals below 0.25 mV may cause inaccurate results.

The amplitude of the electrocardiogram (ECG) signal is critical for reliable frame triggering. Frame triggering should be used only when a clean, noise-free ECG waveform is observed on the ECG display. The ECG signal should be at least 0.25 mV to ensure reliable triggering when the system is used in the presence of the electromagnetic phenomena described in this section and elsewhere in your system user information.

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon that results in the flow of an electrical charge from a higher charged object or person to a lower charged object or person. ESD is most prevalent during conditions of low humidity, which can be caused

by heating or air-conditioning. During low humidity conditions, electrical charges naturally build up on individuals and objects and can create static discharges.

The following cautions can help to reduce ESD effect:

CAUTIONS

- Do not touch transducer connector pins or the system's transducer receptacle.
- Handle the transducer by the metal connector shell.
- Make contact with a metal surface of the system before connecting a transducer to the system.
- On connectors labeled with the ESD sensitivity symbol  , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

Also, your service representative can install the antistatic chain provided with the system.

NOTE

Electrostatic discharges (ESDs) may cause the ECG heart rate display to increase by 10% to 15% for a few seconds after the discharge. However, the ECG heart rate display will return to normal within 4 seconds.

Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified in the table. The customer or the user of the system should ensure that it is used in such an environment.

Electromagnetic Emissions: Environment Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions, CISPR 11	Group 1	The system uses only RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

Approved Cables for Electromagnetic Compliance

Cables connected to the system may affect its emissions. Use only the cable types and lengths listed here.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Cables

Cable	Type	Length
ECG 3-lead safety connector patient trunk cable, AAMI	Shielded	2.7 m (9 ft)
ECG 3-lead safety connector patient trunk cable, IEC	Shielded	2.7 m (9 ft)
ECG Aux input	Shielded	<3 m (<9.8 ft)
Video output	Shielded	Any
LAN	Twisted pair	Any
Foot switch cable (included with foot switch)	Shielded	3 m (9.8 ft)
USB	Shielded	<3 m (<9.8 ft)

Approved Transducers for Electromagnetic Compliance

The imaging transducers used with the system may affect its emissions. The transducers listed in "Clinical Options and Transducers" on page 170, when used with the system, have been tested to comply with the Group 1, Class A emissions, as required by International Standard CISPR 11. Use only those transducers.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Accessories for Electromagnetic Compliance

Accessories used with the system may affect its emissions. The accessories listed here, when used with the system, have been tested to comply with the Group 1,

Class A emissions as required by International Standard CISPR 11. Use only the accessories listed here.

When connecting other accessories to the system, such as a remote video monitor or computer, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 22, Class A-compliant devices, unless otherwise noted.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Accessories

Accessory	Manufacturer	Model Number
Ultrasonic imaging transducer	Philips	Use only Philips transducers
Black-and-white printer	Sony	UP-D897MD
Color printer	Sony	UP-D23MD
Color LaserJet	Hewlett-Packard	Ensure that Philips has authorized the printer and that you have obtained a COTS CD-ROM from your Philips-qualified service representative.
Black-and-white LaserJet printer	Hewlett-Packard	
Inkjet printer	Hewlett-Packard	

Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified here. The customer or the user of the system should ensure that it is used in such an environment.

NOTES

- The guidelines specified here may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- U_T is the AC power voltage before application of the test level.
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Electromagnetic Immunity: Environment Guidance

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	± 6 kV contact, ± 8 kV air	Same as IEC 60601 test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst, IEC 61000-4-4	± 2 kV for power supply lines, ± 1 kV for input/output lines	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	± 1 kV differential mode, ± 2 kV common mode	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_T >95% dip in U_T for 0.5 cycle 40% U_T 60% dip in U_T for 5 cycles 70% U_T 30% dip in U_T for 25 cycles <5% U_T >95% in U_T for 5 seconds	Same as IEC 60601 test level	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, Philips recommends that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	Same as IEC 60691 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF, IEC 61000-4-6	3 VRMS 150 kHz to 80 MHz	0.08 V	For recommended separation distances, see "Recommended Separation Distance" on page 71.
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Cables, transducers, and accessories connected to the system may affect its immunity to the electromagnetic phenomena listed in the preceding table. Use only approved accessories, cables, and transducers to minimize the chance of performance degradation of the system due to those types of electromagnetic phenomena.

CAUTION

If the system is connected to other customer-supplied equipment, such as a local area network (LAN) or a remote printer, Philips cannot guarantee that the remote equipment will work correctly in the presence of electromagnetic phenomena.

Although most remote devices comply with their applicable standards for immunity, those device requirements may not be as stringent as those required for medical equipment. It is the responsibility of the installer and the user of this remote customer-supplied equipment to ensure that it functions properly in the electromagnetic environment where the system is installed. Philips suggests that the installer or the user of such a system consult with experts in the field of electromagnetic compatibility and safety for guidance to ensure the safe and effective use of the created system.

Electromagnetic Interference

Electromagnetic interference may appear in many ways on the system and depends on the mode the equipment is operating in, the imaging control settings, the type of transducer being used, the type of electromagnetic phenomena, and the intensity level of the phenomena.

CAUTION

When interference is present or intermittent, use caution when continuing to use the system.

NOTES

- Electromagnetic phenomena are not always present and may be transitory in nature. It may be extremely difficult to identify the source of the interference.
- The following table describes a few typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference, because it depends on many parameters of the transmitting device, such as the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the imaging system's performance and not be visible in the image. If the diagnostic results are suspicious, other means should be used to confirm the diagnosis.

Typical Interference on Ultrasonic Imaging Systems

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
2D or 3D	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging transducers, white radial bands or flashes in the center lines of the image. For linear imaging transducers, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, or diagonal lines near the center of the image.
Color	Change of operating mode, system settings, or system reset, Brief flashes in the displayed or recorded image.	Color flashes, radial or vertical bands, increase in background noise, or changes in image color.	Color flashes, dots, dashes, or changes in the color noise level.
Doppler	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Horizontal lines in the spectral display or tones, abnormal noise in the audio, or both.	Vertical lines in the spectral display, "popping" noise in the audio, or both.
M-mode	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Increase in the image background noise or white M-mode lines.	White dots, dashes, diagonal lines, or increase in image background noise.

1. Electrostatic discharge (ESD) caused by discharging of electric charge buildup on insulated surfaces or persons.
2. Radio frequency (RF) energy from RF transmitting equipment such as portable phones, handheld radios, wireless devices, commercial radio and TV stations, and so on.
3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

Recommended Separation Distance

The following table provides recommended separation distances, which are guidelines on the distances that any RF transmitting equipment should be kept away from the ultrasound system to reduce the risk of interference with the system. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol:  .

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

NOTES

- For transmitters rated at a maximum output power not listed in the following table, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The information provided here, in conjunction with "Electromagnetic Interference" on page 69, provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz $d = 43.8\sqrt{P}$	80 to 800 MHz $d_T = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.4\sqrt{P}$
0.01	4.4 m	0.12 m	0.24 m
0.1	13.8 m	0.38 m	0.76 m
1	43.8 m	1.2 m	2.4 m
10	138 m	3.8 m	7.6 m
100	438 m	12 m	24 m

The conducted RF test level is 3 V, and the system has a compliance level of 0.08 V. For the system, this means that the imaging system is extremely sensitive to RF interference in the transducer passband. For example, for a 5-MHz imaging transducer, the frequency range of interference from a 3-V/m field may be from

2 to 10 MHz and manifest itself as described in "Electromagnetic Interference" on page 69.

The 0.08-V level is where the interference becomes acceptable to some clinical specialists.

Sensitivity to interference is dependent on operating mode and imaging control settings. The order of increasing sensitivity to interference as a function of operating mode is 2D mode, 3D mode, M-mode, Color mode, PW Doppler mode, and CW Doppler mode. The system is more sensitive to interference in the CW Doppler or PW Doppler operating modes, but the probability of interference is lower than in 2D mode or Color mode, because the susceptible frequency range is lower. Therefore, you are more likely to see interference in 2D or Color modes.

As an example, if a portable transmitter has maximum radiated power of 1 W and an operating frequency of 156 MHz, it should only be operated at distances greater than 1.2 m (3.9 ft) from the system. Likewise, a 0.01-W Bluetooth wireless LAN device operating at 2.4 GHz should be placed no closer than 0.24 m (9.5 in) from any part of the system.

Avoiding Electromagnetic Interference

A medical device can either generate or receive electromagnetic interference. The EMC standards describe tests for both emitted and received interference. Emission tests deal with interference generated by the device being tested. Philips ultrasound systems do not generate interference based on the tests described in the referenced standards.

An ultrasound system is designed to receive signals at radio frequencies and is therefore susceptible to interference generated by RF energy sources. Examples of other sources of interference are medical devices, information technology products, and radio and television transmission towers. Tracing the source of radiated interference can be a difficult task. Customers should consider the following in an attempt to locate the source:

- Is the interference intermittent or constant?

- Does the interference show up only with one transducer or with several transducers?
- Do two different transducers operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a transducer or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the transducer or printer can result in reduced electromagnetic interference.

The answers to these questions will help determine if the problem resides with the system or the scanning environment. After you answer the questions, contact your Philips service representative.

Use Restrictions Due to Interference

The physician needs to determine if an artifact caused by radiated interference will have a negative impact on image quality and the subsequent diagnosis.

3 System Overview

Use this section to acquaint yourself with the ultrasound system and its components.

System Capabilities

The CX50 Ultrasound System is intended for adult cardiac applications and analysis. The optional cart is ergonomically designed to be both highly mobile and adjustable for a range of users and operating conditions. You can use the system for 2D, M-mode, Doppler, and Color imaging.. Stress echocardiography is an option on the system. QLAB Advanced Quantification Software plug-ins are also available as options. The system supports a sector transducer, a matrix transesophageal transducer, and a CW Doppler probe. The system provides measurement tools, analysis options, and DICOM network capabilities. The system is not intended for fetal use.

Measurements

The system provides tools for measuring the size, speed, or duration of image data. In calculations, the following application-specific tools are available:

- 2D Depth
- Distance
- Ellipse
- Continuous Trace
- Volume
- Heart Rate
- Time/Slope
- HighQ

After you perform measurements, the system makes the pertinent calculations and organizes the measurements, calculations, and patient information into a patient report. For information, see the Help. To display Help, press the **Help** key.

Transducer Types

Available transducers include sector, transesophageal, and CW. Applications for specific transducers are listed in "Clinical Options and Transducers" on page 170.

Image Acquisition and Review

You can acquire and save a single frame or a cineloop sequence. The frame or cineloop sequence is saved in the patient study, and a thumbnail of it is available in the live imaging display and the Review display. Images and cineloop sequences are stored on the system hard drive, and also can be stored on CDs, DVDs, and USB devices, or sent over a network to an archive server or a printer.

Stress Echo capabilities also use the ability to acquire and review image loops.

Peripheral devices are available for recording images and study data. You can connect a black-and-white page printer, a color page printer, or a report printer.

Patient Data Protection

The data security feature, if implemented on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log on to the system using a password. When you are finished using the system, you can log off manually, or you can simply shut down the system, which logs you off automatically.

This data protection feature can be used to help meet the requirements of the U.S. Health Insurance Portability and Accountability Act (HIPAA), which became effective April 2003.

For more information on protecting patient data, see "System Security" on page 133.

System Options

In addition to the standard features available in the system, other features are available as purchasable options. The types of options available include clinical

options, QLAB Advanced Quantification Software, imaging capabilities, and connectivity capabilities.

Imaging Options

Once purchased, the imaging option listed here is available as supported by the current transducer and application:

- Stress Echo protocols

Connectivity Options

The following connectivity capabilities are available as purchasable options on your system:

- DICOM networking
- DICOM structured reporting

Clinical/Analysis Options

Clinical options are available on the system. Clinical options include corresponding analysis packages. The following clinical option is available:

- Adult Echo

Calculations

Calculations are organized in collections for the applications included in the system. The system uses measurement values to make calculations and create a patient report. For more information on using calculations, see the Help on your system.

The calculations in the system are based on medical references, which are listed in the "References" section of the Help.

QLAB Advanced Quantification Software Options

The following QLAB Advanced Quantification Software plug-ins are available as separate options:

- ROI (Region of Interest) quantification tools
- SQ (Strain Quantification) basic
- TMQ (Tissue Motion Quantification)

NOTES

- Instructions for using the QLAB plug-ins are included in QLAB Help, which is available by pressing the **Help** key while QLAB plug-ins are active.
- To ensure viewing compatibility of your QLAB Advanced Quantification files on a PC, ensure the QLAB software on your PC is the same version as that on your system.
- When acquiring images, do not have both black-and-white and color suppression enabled.

Stress Echocardiography

Stress Echocardiography (Stress Echo) is a protocol-driven study that allows a cardiologist to assess cardiac wall motion at various heart rates by acquiring views of the heart at different stages of the study. Stress Echo includes these Philips protocols:

- Exercise 2-Stage
- Exercise 3-Stage
- Pharmacological 4-Stage

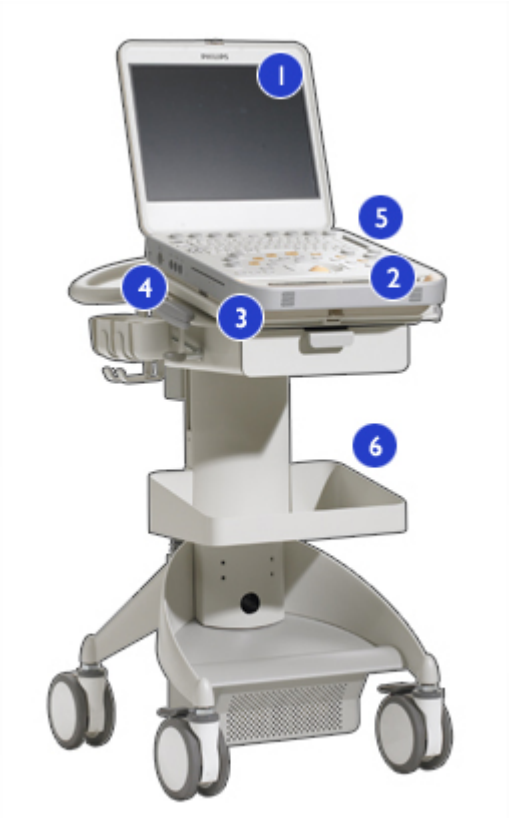
You can create custom presets based on those protocols.

Data Security

A data security feature is available to help maintain the confidentiality of archived patient files. With this feature, access to patient study files is restricted to authorized personnel through password protection.

System Components

The components include the monitor, control panel, DVD drive, transducer receptacle, ECG/physio receptacle, and AC adapter/battery charger. The system can be attached to an optional cart. The cart height is adjustable to accommodate a range of operator heights and operating positions.

	Description	System Components
1.	Monitor	
2.	Control panel	
3.	DVD drive	
4.	ECG/physio receptacles	
5.	Transducer receptacles	
6.	Optional cart	

Video Monitor

On the optional cart, the system is adjustable to accommodate different operating heights. The monitor can be latched in its closed position to protect the flat-panel display and the control panel while moving the system (see "Moving the System" on page 106). Two light sensors on the control panel can automatically reduce the brightness of both the monitor and the controls on the control panel when room lighting is dim.

Control Panel

The control panel contains the imaging controls. These controls include buttons, knobs, TGC and LGC slide controls, and a trackball. The control panel also allows you to select transducers, enter patient data, review and annotate images, perform measurements and calculations, and change setups.

Eight quick key controls are located along the top of the control panel. Each control corresponds to a display above it on the monitor, which may contain one or two functions. Quick key controls are specific to the current operating mode.

The keyboard is used to enter patient data, comments, and text annotations on images.

On/Off (Power) Switch

The On/Off control is located on the control panel. When the system is off, pushing this control brings the system into a fully operational state. Pushing this control again turns off the system.

On/Off Switch

Data Storage

You can store study data and images onto removable media using the DVD drive. The system hard drive is located inside the system. You can also store study data, system setup data, and images onto USB devices connected to the USB port on the system. For more information, see "DVD and USB Devices" on page 141.

DVD Drive

Peripherals

Peripheral devices are available for printing images and studies. You can connect a black-and-white page printer, a color page printer, or a report printer.

Peripheral devices can be installed in the system cart or can be external to the cart. External peripheral devices cannot be placed on the system cart, and they must be disconnected before moving the cart.

Transducer Receptacles and Cable Management

The system includes one receptacle for imaging transducers and one receptacle for a pencil probe. When a transducer is not in use, store it in one of the transducer holders on the system cart, and place the transducer connector in one of the holders on the back of the cart. Always use the cable management system to prevent cables from being stepped on or run over by the cart wheels.

Transducer Receptacles

	Description	Receptacles
1.	Imaging receptacle	
2.	CW Doppler receptacle	

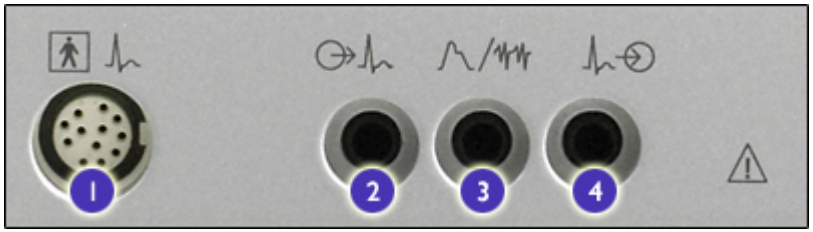
Transducer Holders and Cable Hangers

	Description	Transducer Holders and Cable Hangers
1.	Transducer holders	
2.	Cable hangers	

Physio (ECG) Receptacles

For physio support, your system includes input receptacles for both high-level and low-level ECG, pulse, phono, and auxiliary signals. Also, there is an analog output receptacle for external monitoring devices. The ECG receptacles are on the left side of the system.

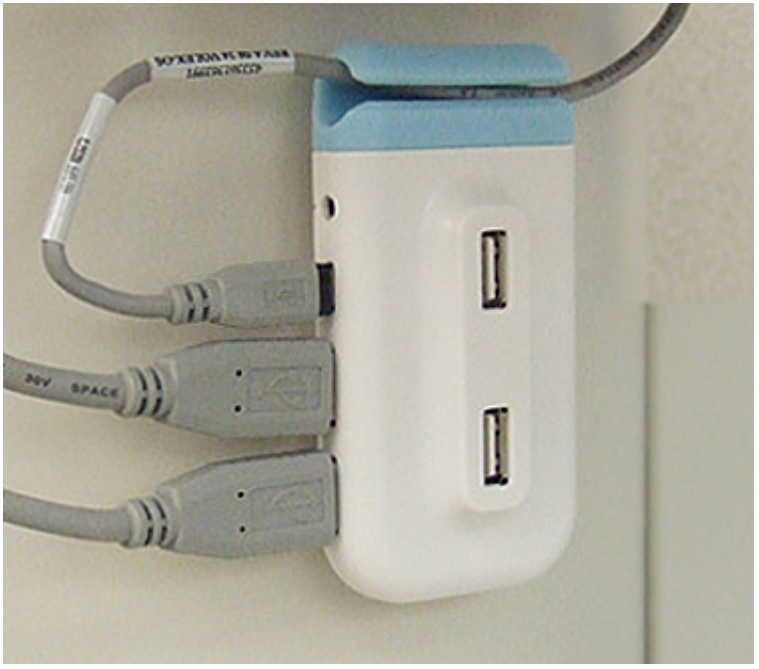
Physio Receptacles

	Description	Physio Panel
1.	Low-level ECG input	
2.	Analog output	
3.	Pulse/Phono/Aux 2 input	
4.	External ECG/Aux 1 input	

USB Hub

The USB hub on the front of the optional system cart provides USB ports for peripherals. The hub is connected to a USB port on the system.

USB Hub



Wheel Controls

On the optional cart, all four wheels swivel to aid in maneuvering the system. The front wheels on the cart have wheel controls that you can engage and disengage independently. Brakes help keep the cart stationary while in use.

Wheel Controls

4 *Preparing the System*

The information and procedures in this section will help you prepare the system for use. Preparations include connecting external devices, setting up for moving, and ensuring that system operating requirements are met.

Connecting Devices

In addition to the devices installed in the system cart, the system supports external devices. These devices include printers and a color monitor.

WARNINGS

- When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1-1 and test the system to those requirements. For more information on peripheral devices, see "Electrical Safety" on page 21. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1-1.

CAUTION

Using accessories, transducers, peripherals, or cables not supplied with the ultrasound system or recommended by Philips can affect the system in the form of increased emissions or decreased immunity to external EMI/EMC occurrences.

NOTE

Any device that is not purchased from Philips and that is not installed by Philips personnel is not covered under a Philips service agreement or warranty, and it will not be serviced by Philips.

External Printers

You can connect the following external printers to your system:

- UP-D23MD color printer
- UP-D897 black-and-white image printer
- Sony UP-D55 large-format multi-image color printer
- Black-and-white report printers: HP LaserJet 1320, P2015, 2430, or P3005
- Color report printers: HP Color LaserJet 3800; Color Deskjet 2460 or 6988; Officejet J5780; or Inkjet 1200D

WARNING

Images printed on a report printer are intended only for reference and should not be used for diagnostic purposes.

For additional information, see "Configuring Local Printers" on page 91 and the "Printing" section in the Help.

Connecting an External Printer

WARNINGS

- When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601–1–1.

1. Turn off the system and unplug the power cord from the power source.
2. Connect a standard USB cable between the USB port on the printer and a USB  port on the system.
3. Connect the printer's power cord into the back of the printer, and plug the other end into an appropriate power source (see Warnings).
4. Turn on the printer, and then turn on the system.

Configuring Local Printers

You can add a local printer to the system and then associate it with a print control or with the **Acquire** control in the setups. The print control, on the system control panel, is labeled **Print**. You can print only to a printer that has been selected. You can also change other printing parameters.

NOTE

Before adding a local printer, connect the printer to the ultrasound system as described in "Connecting an External Printer" on page 91.

1. Press the **Setup** key.

2. Click the **Peripherals** tab.
3. Select a printer from the **Print** menu in the **Peripheral Selection** area.
4. To assign a printer to the **Acquire** key, select a printer from the **Acquire** menu.
5. If you have assigned a printer to the **Acquire** key, click **Auto Print**, and then click one of the following:
   - **Batch Mode**, to print all images at the end of the study
   - **Send As You Go**, to print each image as it is acquired
6. Click **Config** and change the printer configuration as needed.
7. Click **OK**.
8. To print multiple images per sheet, select a key from the **Key** menu.

WARNING

Multi-image prints made on small-size paper are intended only for reference and should not be used for diagnostic purposes. Text annotation and scaling markers may not be visible on such prints.

9. To specify a layout for multiple images per sheet, click **Layout** and select options in the **Print Page Layout** dialog box.
10. Click **Apply** to apply your changes to this session only, or click **Save** to save your changes to a preset.

Connecting the Optional Foot Switch

Insert the connector on the foot switch cable into a USB  port on the system.

Connecting an External Color Monitor

You can connect a compatible external color monitor to the VGA video output  receptacle on the right side of the system. This receptacle provides

standard RGB output for analog monitors, at a screen resolution of 1400 x 1050 (SXGA+).

WARNINGS

- When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1-1 and test the system to those requirements. If you have questions, contact your Philips representative.
- Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601–1–1.

1. Turn off the system and unplug the power cord from the power source.
2. Connect the data cable from the monitor to the video output receptacle on the system.
3. Connect the monitor's power cord to an appropriate power source (see Warnings).
4. Turn on the monitor, and then turn on the system.

Connecting the System to a Network

To use connectivity features, the system must be connected to a network. The ethernet receptacle on the system supports both 10Base-T and 100Base-T formats. The system is configured for network connectivity by a Philips field service engineer or your network administrator.

For information on changing the network configuration for the system, see "System Administration" in the Help. To display Help, press the **Help** key.

1. Turn off system power.
2. Connect one end of the provided network connection cable to the wall receptacle for your network.

3. Connect the other end of the cable to the network receptacle on the system.

Attaching the System

The optional system cart includes latches for securely attaching the system.

CAUTION

Never move the cart with the system on it, unless the system is properly attached to the cart.

1. Slide the back of the system onto the rear latch so that the pins seat fully into the holes in the system. You may need to open and close the rear latch.
2. Lower the front of the system onto the cart until the front latch snaps into place.
3. Ensure that both latches are fully engaged and that the system is firmly attached to the cart.

System Configuration

The ultrasound system is configured using the **System** setups. The configuration information for the system includes the IP address, port number, and other attributes required for transmitting images and other study data across a network. The system must be configured before you use either the standard network support or the capabilities available through the DICOM Networking option.

Standard Network Support

The system supports standard wired and wireless network functions, which include printing to local printers and report printers. Additional network capabilities are available in the DICOM Networking option.

DICOM Networking Option

The DICOM Networking option permits network transfer of image and report information. The system conforms to the Digital Imaging and Communications in Medicine (DICOM) standard, version 3.0. Centralized printers, print servers, network file servers, and review workstations that comply with the DICOM standard can take advantage of the DICOM Networking option.

With the DICOM Networking option, you can store ultrasound images on DICOM-compatible file servers or storage devices and review them using a workstation. You can also print studies directly. Capabilities include support for DICOM services such as Modality Worklist, Performed Procedure Step, and Storage Commit. Additionally, the DICOM Networking option includes the DICOM Structured Reporting option, which allows you to transfer tagged report data to a PC, server, or other device.

The DICOM Networking option is initially set up by your Philips Ultrasound field service engineer or the system administrator. The **DICOM** setups are available from the **System** setups display or by clicking  or  . After you select **DICOM**, the options available to you depend upon the configuration of your system. The DICOM Networking option requires additional levels of setup.

Once the ultrasound system is configured, it remains that way through power cycles until you reconfigure it.

Configuration Information

Before you can use either the standard network support or the capabilities provided by the DICOM Networking option, the system must be configured to communicate on the network.The system configuration information must contain the correct AE title, port number, IP address, and subnet mask for each device on the network, including the system itself.

The following list describes configuration information:

Value	Description
AE (Application Entity) Title	(1) An arbitrary name, but a required field, for DICOM configuration. (2) In the **DICOM** setups, a field into which you enter the AE title.
Gateway	(1) A device or system that connects two networks together. (2) In the **DICOM** setups, a field into which you enter the gateway address of the ultrasound system. This field requires a four-byte IP address with each byte separated by a dot and in the range of 0 to 255.
IP Address	(1) A four-byte IP address with each byte separated by a dot and in the range of 0 to 255. A required field for DICOM configuration of the ultrasound system or device. (2) In the **DICOM** setups, a field into which you enter the IP address.
Port Number	(1) A number in the range of 0 to 65,535, found in the DICOM Conformance Specification for the ultrasound system or device. A required field for DICOM configuration of the ultrasound system or any device configured for DICOM operation. (2) In the **DICOM** setups, a field into which you enter the port number.
Subnet Mask	(1) A four-byte IP address with each byte separated by a dot and in the range of 0 to 255. A required field for DICOM configuration of the ultrasound system. (2) In the **DICOM** setups, a field into which you enter the subnet mask of the ultrasound system.

Entering System Network Settings

You must enter settings for your system before you connect your system to the network. If you have questions, see your network administrator.

NOTES

- You cannot make DICOM setup changes if you have a study open or if any DICOM jobs are pending. Close the open study and complete or delete pending DICOM jobs first. A message is displayed if you have pending jobs.
- If you change DICOM presets, the new preset's network settings are not applied immediately. You must first apply the network settings before trying to ping or create a new DICOM device in the new preset.

1. To avoid the possibility of conflicting IP addresses in static IP configurations, do not connect the LAN cable (if you are using a wired connection) or the wireless network adapter (if you are using a wireless connection) to the system. If it is already connected, disconnect it.
2. Press the **Setup** key.
3. On the **System** tab, click **DICOM**.
4. Click the **DICOM Preset** tab.
5. On the **Change DICOM Preset** menu, select the preset that you want to change.
6. Click **Change Settings For Current Preset**.
7. Click the **This System** tab.
8. In the **System Name** area, change the **PC Name** to that specified by your network administrator and enter the **AE Title** for your system specified by your network administrator.

NOTES

- The AE title for each device on the network must be unique.
- AE titles are case sensitive. (That is, PACS1 is different from Pacs1.)
- In many institutions, the AE title is derived from the **PC Name**, which must be unique across the institution's network.

9. In the **System Port Number** area, type, or click the arrows to change, the port number specified by your network administrator.

NOTES

- The default port number, 104, is assigned to ultrasound systems at most institutions.
- If the network is configured for DHCP, then the network administrator may need to know the system's MAC address, which is displayed in the **Network Settings** area.

10. To apply the same AE title and port number to all DICOM presets that you create, in the **Common Settings** area, click **Press To Apply the Same AE Title and Port Number to All DICOM Presets**.
11. In the **Network Settings** area, click **TCP/IP Properties**.
12. In the **Internet Protocol (TCP/IP) Properties** dialog box, enter the **IP Address**, the **Subnet Mask**, and any other network parameters specified by your network administrator.
13. Click **OK**.
14. Connect the LAN cable (if you are using a wired connection) or the wireless network adapter (if you are using a wireless connection) to the system. After about 10 to 20 seconds, click **Network Administration**, verify that the TCP/IP properties that you entered are displayed in the **Information Window**, and verify that the **Network Status** is **Connected**.

NOTES

- To refresh the window, click **ipconfig** for summary information or **ipconfig/all** for detailed information.
- If DHCP is configured, you may need to release the connection and then renew the connection to obtain a DHCP lease. To do this, click **ipconfig/release** and then click **ipconfig/renew**.
- To verify that a particular server is on the network, in the **TCP/IP Ping a Networked Server** area, type the server's IP address or DNS name and click **Ping**. The system then performs a TCP/IP ping and displays the results in the **Information Window**.

15. Click **Close**, and then click **Close** again.

Changing the PC Name

1. Press the **Setup** key.
2. On the **System** tab, click **DICOM**.
3. Click the **DICOM Preset** tab.
4. Select a preset from the **Change DICOM Preset** menu.
5. Click **Change Settings for Current Preset**.
6. Click the **This System** tab.
7. In the **System Name** area, click **Change** next to the **PC Name** field.
8. Enter the new computer name in the **Change Computer Name** dialog box.
9. Click **OK**.
10. Click **OK** to confirm the name change.
11. Shut down the system and restart it.

NOTE

After you change the **PC Name**, the system disables all DICOM options until you restart the system. After you restart the system, all installed DICOM options are available again.

Wireless Networking

The system supports wireless networking. Wireless networking does not require the DICOM Networking option. The system supports only one wired or wireless network connection at a time.

The system supports the IEEE 802.11 b/g wireless networking specification.

Use only Philips-approved USB wireless network adapters with the system.

NOTES

- Wireless network settings are not stored with DICOM presets, so you cannot back up or restore wireless settings.
- Wireless connection quality can be affected by many factors. The system may experience a connection interruption while a network job is in progress. If this occurs, the job remains in the job queue. When the connection is restored, the system resumes the job automatically.
- For more information about your wireless network adapter, see the documentation that accompanies the adapter.
- It is your responsibility to configure the wireless network security mechanisms that are compatible with your network. See "Configuring Wireless Network Properties" on page 102.

Enabling a Wireless Network Connection

When you enable a wireless network connection on the system, it appears on the network as **Philips Medical Systems Wireless**.

Wireless networks appear in the **Wireless Properties** dialog box. The system automatically tries to connect to the network that is first in the list of preferred networks. If the first network is unavailable, the system tries to connect to the next network in the list.

1. Enter system network settings. See "Entering System Network Settings" on page 96.
2. Plug the wireless network adapter into the USB port on the side of the system.

NOTE

After the connection is enabled, you can remove and reconnect the network adapter without disabling the connection.

3. Press the **Setup** key.
4. Click the **System** tab.
5. Click **DICOM**.

6. Select a preset from the **Change DICOM Preset** menu, and click **Change Settings for Current Preset**.
7. On the **This System** tab, select **Wireless** from the **Select Network Adapter** menu.
8. Click **Wireless Properties** and do either of the following:

   - Select the wireless network to which you want to connect from the **Preferred Networks** list, and click **Move Up** to move it to the first position in the list. (Click **Move Down** to move a wireless network lower in the list.) Click **Properties** to adjust the properties of the wireless network. See "Configuring Wireless Network Properties" on page 102.
   - Click **Add** to add a wireless network and configure its properties. See "Configuring Wireless Network Properties" on page 102.

   Icons in the **Wireless Properties** dialog box indicate the connection status of each wireless network:  (connected) or  (disconnected).
9. Click **Advanced** and select one of the following:

WARNING

Allowing the system to connect to ad-hoc networks may result in unintended connections to networks outside of your facility, which may make servers unavailable and could expose protected health information.

- **Any Available Network (Access Point Preferred)** for the system to use both infrastructure mode and ad-hoc networks. (Infrastructure-mode wireless networks are listed before ad-hoc wireless networks in the **Preferred Networks** list.)
- **Access Point (Infrastructure) Networks Only** for the system to use only infrastructure mode wireless networks.
- **Computer-to-Computer (Ad Hoc) Networks Only** for the system to use only ad-hoc wireless networks.
- **Automatically Connect to Non-Preferred Networks** to specify that the system can connect to wireless networks that are not in the **Preferred Networks** list.

NOTE

If you select **Automatically Connect to Non-Preferred Networks**, the system can connect to any wireless network, including unexpected or undesired networks.

10. Click **Close**, and then click **OK.**

Configuring Wireless Network Properties

Once you have enabled a wireless network connection, you can configure security and connection settings, including authentication and encryption methods and keys.

1. Press the **Setup** key.
2. Click the **System** tab.
3. Click **DICOM**.
4. Select a preset from the **Change DICOM Preset** menu, and click **Change Settings for Current Preset**.
5. On the **This System** tab, select **Wireless** from the **Select Network Adapter** menu.
6. Click **Wireless Properties**.
7. In the **Wireless Properties** dialog box, select the wireless network that you want to configure and click **Properties**.
8. On the **Association** tab, specify wireless network key settings:
   - Specify the method of authentication on the wireless network by selecting an option from the **Network Authentication** menu. The system does not support enterprise authentication (the **WPA** and **WPA2** authentication methods).
   - Specify the method of encryption on the wireless network by selecting an option from the **Data Encryption** menu. The options available depend upon the authentication method.
   - Specify and confirm a network key by typing a key used for authentication and encryption in the **Network Key** and **Confirm Network Key** fields.

Availability of these fields depends upon the methods chosen for network authentication and encryption.

- Select the index in which the network key is stored (1 to 4 keys) from the **Key Index** menu. Select **This Key Is Provided to Me Automatically** if the key is provided on the wireless network adapter. Availability of these options depends upon the methods chosen for network authentication and encryption.
- If the wireless network uses infrastructure mode or ad-hoc mode, select **This is a Computer-to-Computer (Ad Hoc) Network**.

9. On the **Connection** tab, select **Connect When This Network is in Range** to automatically connect to the wireless network when the system detects the wireless network. This option must be selected for the system to be able to establish a connection to the wireless network.
10. Click **OK**.

CAUTION

Do not modify options on the **Authentication** tab. These options are enabled only if the network authentication method chosen supports enterprise authentication (**WPA** or **WPA2**). The system does not support enterprise authentication.

Removing a Wireless Network

If you no longer use a wireless network, you can remove it from the list of preferred networks.

1. In the **Wireless Properties** dialog box, select the wireless network that you want to remove from the list of preferred networks, and click **Remove**.
2. Click **OK**.

Troubleshooting Wireless Network Connections

If the system's network connection is not functioning, as indicated by the  (Wireless Network Disconnected) icon on the display, or if the wireless network adapter does not function correctly,troubleshoot the network connection.

Do any of the following:

- Disconnect and then reconnect the wireless network adapter.
- Ensure that only one wireless network adapter is connected to the system.
- Use **Repair Network Connection** to locate and select the wireless network adapter.
- If the wireless network adapter is connected to a USB hub or extender, connect the adapter directly to the system.
- Always connect the wireless network adapter to the same USB port.

Remote Access

You can configure the system to enable remote service by a Philips field service representative. For example, a Philips representative could remotely operate the system to perform diagnostic tests.

During a remote-access session, the system displays a message indicating that a remote session is in progress.

NOTE

You must disconnect all transducers from the system before a remote access session.

To enable remote service, the system must be:

- Connected to the Philips Remote Service Network (RSN) by a Philips representative
- Registered on the Philips remote access server by a Philips representative
- Configured to enable remote access

For more information on remote service, contact your Philips representative.

Configuring the System to Enable Remote Access

CAUTION

If the LAN connection your Philips representative configured to connect your system to the RSN is no longer necessary after a remote service session, remove the connection to avoid a possible isolation compromise.

1. Press the **Setup** key.
2. Click the **Service** tab.
3. Select **Enable Remote Session** in the **Remote Service** area.

NOTE

If you deselect **Enable Remote Session** and then click **Apply** at any time during a remote session, the session is terminated.

4. To allow the field service representative access to patient studies, select **Allow Open Studies**.
5. Click **Apply**, and then click **Close**.The system displays the **Confirm Remote Session** dialog box. Although this dialog box states that a remote session has been requested, a remote session is initiated only when your Philips representative activates the session.

Repairing Network Connections

If the system's network connection is not functioning, as indicated by the  (Network Disconnected) or  (Wireless Network Disconnected) icon on the display, you can attempt to repair the network connection.

When you repair the network connection, the system locates and selects the network adapter, renews the IP address, refreshes all DHCP leases, and reregisters DNS names. If the DICOM Networking option is installed, the system also updates the current DICOM preset with the TCP/IP settings.

NOTE

If no wireless network adapter is connected, the system prompts you to retry the repair. If you cancel the repair, the system disables the network connection.

1. Press **Pointer**.
2. Click  or  .
3. Click the **Diagnostics** tab in the **DICOM Setup** dialog box.
4. In the **Repair Network Connection** area, click **Repairs**.
5. In the **Repair Network Connection** dialog box, click **Repair**. The system displays information about the repair.
6. Click **Close**.

Moving the System

Before moving a system that is not mounted on a cart, Philips recommends that you disconnect the AC adapter, ECG leads, and transducers. If you will be using the system again within 20 minutes, close the lid without turning the system off to put the system into the low-power portability mode. If you will *not* be using the system within 20 minutes, turn it off before closing the lid and moving the system.

Observe the following warnings and cautions before moving a system that is mounted on a cart.

WARNINGS

- Be aware of the wheels, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Exercise caution when going up or down ramps.
- When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.
- Position external hardcopy devices away from the system. Ensure that they are secure. Do not stack them on the system.
- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

CAUTIONS

- Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.
- Do not roll the system over transducer cables or power cables.
- When transporting the system in a vehicle, avoid exposing the monitor to direct sunlight and do not let the inside temperature of the vehicle exceed 65°C (149°F). Either of these conditions can permanently damage the monitor.

Preparing and Moving

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.

1. Do one of the following:
   - If you will be using the system within 20 minutes, put the system into the low-power portability mode by closing the lid without turning the system off.

- If you will *not* be using the system within 20 minutes, turn off the system by pressing **On/Off**, and then close the lid.

2. If the system is attached to the optional cart, set the circuit-breaker switch on the lower rear of the cart to off ○.
3. Disconnect all external cables, including those to power, network, and external devices.
4. If the system is attached to the cart, secure all cables, transducers, and accessories so that they do not interfere with the wheels.
5. Release the wheel brakes.
6. Move the cart using the handle at the rear of the cart. Do not use the system handle to move the cart.

Setting Up After Moving

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.

CAUTION

If the system behaves abnormally after moving contact Philips Ultrasound Customer Service immediately. The components are installed securely and can withstand considerable shock; however, excessive shock can cause a system failure.

1. With the system in position, connect the power, network, and other cables from the system to the appropriate wall receptacles.
2. Press **On/Off** to turn on the system.

Environmental Requirements

If your system will be used in a variety of locations in your facility, ensure the location can support the system size and other needs noted here.

Physical Dimensions

System Only

- Width: 35.6 cm (14.0 in)
- Height: 39.4 cm (15.5 in) with monitor fully raised; 7.6 cm (3 in) with monitor locked
- Depth: 41.4 cm (16.3 in)
- Weight: 7.1 kg (15.7 lb)

System and Cart

- Width: 51.2 cm (20.2 in)
- Height: 144.8 cm (57.0 in) with monitor fully raised; 113.0 cm (44.5 in) with monitor locked
- Depth: 60.0 cm (23.6 in)
- Weight: 69 kg (152 lb) with printers, AC adapter, transducers, and all cables

AC Adapter

- Width: 12.5 cm (4.9 in)
- Height: 6.7 cm (2.6 in)
- Depth: 20.3 cm (8.0 in)
- Weight: 1.6 kg (3.6 lb)

Data Connections

- Ethernet network (10Base-T and 100Base-T)
- USB 2.0

Modality Interface

DICOM standard

Electrical Parameters

The system contains a power supply designed to work with a voltage range of 100-240 V~, 50/60 Hz at 750 VA. Power must be available through a grounded, hospital-grade outlet.

Pressure Limits

- Operating: 525 mmHg to 795 mmHg (700 hPa to 1,060 hPa)
- Storage: 375 mmHg to 795 mmHg (500 hPa to 1,060 hPa)

Humidity Limits

- Operating: 30% to 85%
- Storage: 15% to 95%

Temperature Limits

- Operating: 10°C to 40°C (50°F to 104°F)
- Storage: -34°C to 65°C (-29°F to 149°F)

5 *Using the System*

The topics that follow will help you understand and use the features of the system.

Turning the System On and Off

The **On/Off** control is located on the upper left section of the control panel. When the system is on, the **On/Off** control is lit.

CAUTION

If a charged battery is not installed in the system, do not unplug the AC adapter from the wall outlet until the system is completely off. If you unplug the AC adapter before the shutdown message appears and a charged battery is not installed in the system, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.

NOTES

- Pressing and holding the **On/Off** control to force the system to shut down can cause the same problems as prematurely unplugging the system. Wait 90 seconds (or 3 minutes if DICOM activity is occurring) before assuming that the system has failed to shut down normally.
- To break the connection from the main power supply, remove the ultrasound system plug from the wall outlet or remove the AC adapter connector from the system.

1. Do any of the following:
   - When the system is off, press the **On/Off** control to turn it on.
   - When the system is on, press the **On/Off** control to turn it off. A confirmation message appears briefly on the display immediately before the system turns off.

2. If the system does not turn off after 90 seconds (or 3 minutes if DICOM activity is occurring), press and hold the **On/Off** control for 5 seconds to force the system to turn off.

Setting the System Time and Date

The system includes a clock/calendar function, which maintains accurate time and date even when the system is turned off and disconnected from power. The system uses the clock/calendar function to display the time and date on the imaging display, and to provide a time stamp on patient studies and acquired images. The system automatically adjusts the date for leap years but does not automatically update for daylight saving time.

1. Press the **Setup** key.
2. Click the **System** tab.
3. Click **Date/Time**.
4. In the **Time** box, do any of the following:
   - To set the time, highlight the hours, minutes, or seconds, and then press the **PgUp** key or the **PgDn** key.
   - To select a.m. or p.m., highlight **AM** or **PM**, and then press the **PgUp** key or the **PgDn** key.
5. Under **Date**, do any of the following:
   - To change the day, click it in the calendar.
   - To change the month, click a month in the menu.
   - To change the year, highlight it and then press the **PgUp** key or **PgDn** key on the keyboard.
6. To save your changes, click **OK** and then click **Close**.

System Cart

The compact optional cart provides storage for transducers and supplies, adjustable system height, and wheels that swivel for maneuverability. The cart provides isolated power for the system and for peripheral devices.

Attaching the System

The optional system cart includes latches for securely attaching the system.

CAUTION

Never move the cart with the system on it, unless the system is properly attached to the cart.

1. Slide the back of the system onto the rear latch so that the pins seat fully into the holes in the system. You may need to open and close the rear latch.
2. Lower the front of the system onto the cart until the front latch snaps into place.
3. Ensure that both latches are fully engaged and that the system is firmly attached to the cart.

Adjusting Cart Height

You can adjust the height of the cart to suit different operating positions and operator heights.

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.

CAUTION

Do not use the system handle to raise or lower the system. Use only the grips on either side of the cart for this purpose.

1. Ensure that the system is securely attached to the cart.
2. Lift the lever on the left side of the cart and raise or lower the system using the grips on the cart.
3. Release the lever to lock the position.

Height-Adjustment Lever and Grip

Using the Wheel Controls

WARNINGS

- Never park the system on an incline.
- The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

All four wheels on the system cart swivel to aid in maneuvering the system. The front wheels have wheel controls that you can engage and disengage independently. Brakes help keep the cart stationary while in use.

Wheel Controls

Wheel unlocked	
Wheel locked	

- To engage the brake, press the front of the lever.

- To release the brake, press the back of the lever.

Monitor Settings

You can change the monitor brightness and tint in the setups and by using keyboard shortcuts. The system can automatically optimize the brightness of the controls and the image on the monitor based on ambient light. This feature ensures that display brightness conforms to the DICOM Grayscale Standard Display Function.

Changing the Monitor Tint

You can change the tint of the monitor image. The tint setting affects only the appearances of images on the monitor; it does not affect saved or exported images. The following settings are available:

- **sRGB** (For routine use, Philips recommends this setting.)
- **1-4**

Do one of the following:

- Press **Ctrl**+**T** repeatedly to cycle through the tint settings.
- On the **System** tab in the setups, click a setting for **Monitor Tint**, and then click **Apply**.

Changing the Monitor Brightness

You can change the brightness of the monitor display. The brightness setting affects only the appearances of images on the monitor; it does not affect saved or exported images. Also, the system can automatically control the brightness of both the monitor and the controls on the control panel, based on room lighting (see "Automatic Brightness Control" on page 120). When automatic brightness is enabled, the **Monitor Brightness** setting in the setups allows you to fine tune the automatic brightness setting.

NOTE

The monitor backlight automatically turns off if the system controls are not used for 15 minutes. Using any control turns it on again.

Do one of the following:

- Press **Ctrl+M** repeatedly to cycle through the brightness settings.
- On the **System** tab in the setups, click a setting for **Monitor Brightness**, and then click **Apply**.

System Controls

The system includes a variety of controls, all of which are located on the control panel. These controls include imaging controls, quick keys, and the keyboard.

Control Panel

The control panel contains the imaging controls. These controls include buttons, knobs, TGC and LGC slide controls, and a trackball. The control panel also allows you to select transducers, enter patient data, review and annotate images, perform measurements and calculations, and change setups. For information on how the system indicates control availability and the status of modes, see "Control Status" on page 118.

Eight quick key controls are located along the top of the control panel. Each control corresponds to a label, displayed above it.

The keyboard is used to enter patient data, comments, and text annotations on images. Keys along the top of the keyboard provide a variety of functions, including patient data entry, physio, protocols, the setups, and the Help.

Control Panel

Control Status

The color and state of the lighted controls and their labels indicates the availability of the controls and the status of modes.

Definitions of Control Backlight Colors and States

Backlight Color or State	Control Status
Off	Control is unavailable
Amber	Control is available
Green	Control or mode is active or on (only on mode controls and certain other controls)

Changing Control Panel Brightness

You can change the brightness of the lit controls on the control panel. Also, the system can automatically control the brightness of both the monitor and the controls on the control panel, based on room lighting (see "Automatic Brightness Control" on page 120). When automatic brightness is enabled, the **Control Panel Brightness** setting in the setups allows you to fine tune the automatic brightness setting.

NOTE

The monitor backlight automatically turns off if the system controls are not used for 15 minutes. Using any control turns it on again.

1. Do one of the following:
   - Press **Ctrl+B** repeatedly to cycle through the control panel brightness settings.
   - On the **System** tab in the setups, click a new setting for **Control Panel Brightness**.
2. Click **Apply**.
3. Click **Close**.

Automatic Brightness Control

The system can be set to automatically reduce the brightness of both the monitor and the controls on the control panel when room lighting is dim. This feature conserves battery power and helps to ensure that display brightness conforms to the DICOM Grayscale Standard Display Function.

Enabling Automatic Brightness Control

The **Monitor Brightness** and **Automatic Brightness Control** settings in the setups allow you to fine tune the automatic brightness function, when it is enabled.

1. Press the **Setup** key.
2. Click the **System** tab.
3. Select or deselect **Automatic Brightness Control**.
4. Click **Apply**.
5. Click **Close**.

Quick Key Controls

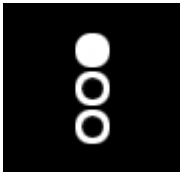
Quick key controls are located along the top of the control panel. Two rows of labels for quick key functions and settings appear along the bottom of the display. Each column of labels corresponds to a quick key control below it on the control panel. Those quick key controls are used to select imaging features and settings. The functions of the quick key controls change depending on the mode, the application, the preset, and the transducer.

Two labels appear above each quick key control. The top label is the function that is invoked by *pressing* the control. The bottom label is the function that is invoked by *turning* the control. In some cases, two rotary functions are available for a quick key. Only one of the two functions can be active at any time. When two rotary functions are available, the top label shows both functions that are available. The bottom label shows which function is currently selected. Pressing

the quick key control selects which function is active. Turning the control changes the settings for the active function.

In most modes, there are two or more pages of quick key functions available. Use the **Next** control to display the next available page of quick key functions. An indicator above the **Next** control shows how many pages of functions are available and which one is selected. For example, in this figure, the first of three available quick key pages is selected.

Quick Key Page Indicator



The monitor automatically dims if system controls are not used for 20 minutes. Quick key labels are not visible when the monitor is dimmed. Using any control turns the monitor on again.

Using Quick Key Controls

- Press the quick key control to change the setting of the top function.
- Turn the quick key control to change the setting of the bottom function.
- If two rotary functions are available for a quick key control, press the control to select which function is active. Then turn the control to change the setting of the active function.
- To display the next page of quick key functions, press **Next**.

System Keyboard

You can use the keyboard to enter patient data, study comments, image annotation, and your logon password. The function keys along the top of the

keyboard are used to perform various functions, such as entering patient data, selecting transducers, reviewing images, ending an exam, changing setups, and displaying the system Help.

Typing Special Characters

The World keys are labeled with a globe. They appear on either side of the spacebar. Use a World key to type the characters that appear on the right side of some keys on the keyboard.

NOTE

Ensure that the Caps Lock is off (the Caps Lock indicator  should *not* appear on the left side of the status line on the display).

Do any of the following:

- To type a character that appears on the bottom right corner of a keyboard key, press the World key and the special character key simultaneously.
- To type a character that appears on the top right corner of a special character key, press the World key, the **Shift** key, and the special character key simultaneously.
- To type the lower case version of a character that appears on the top right corner of a special character key, press the World key and the special character key simultaneously.

Typing Accented Characters

You can type a letter with a diacritical mark that does not appear on your keyboard (for example, Â).

NOTE

Ensure that the Caps Lock is off (the Caps Lock indicator  should *not* appear on the left side of the status line on the display).

1. Press the key for the diacritical mark you want to type. If the diacritical mark is at the top of the key, press **Shift** while pressing the key (for example,

Shift+**^**). The diacritical mark does not appear until you press the actual letter key.

2. Press the letter key. For an uppercase letter, press **Shift** and the letter key (for example, **Shift**+**A**).

Status Icons

The icons on the display let you control certain features and check the status of tasks.

Icon	Description
	Indicates the status of the **2D Opt** selection; for information, see the "Imaging Modes" section in the Help.
	Displayed when the **Caps Lock** key is on.
	Displayed when the XRes feature is on.
	Displayed when the system is ready for acquisition.
	Displayed when the system is busy acquiring an image. You cannot start another acquisition when this icon is displayed.
	Indicates the status of the wired network: • Green dot: Connected • Red X: Disconnected or error Click the icon to open the **DICOM Setup** dialog box. This icon appears only if the DICOM licensed options are installed.

Icon	Description
	Indicates the status of the wireless network: • Green dot: Connected • Red X: Disconnected or error Click the icon to open the **DICOM Setup** dialog box. This icon appears only if the DICOM licensed options are installed.
	Indicates that the system is running on AC power and indicates battery status. • As shown: Battery is fully charged. • Yellow lightning bolt: Battery is charging.
	Indicates that the system is running on battery power and indicates battery status. • Five blue bands: Battery is fully charged. • Four to two bands: Battery is partially charged. • Single red band: Battery is nearly depleted and should be charged.
	Indicates that no user is logged onto the system. Click the icon to log on.
	Indicates that a user is logged onto the system. Click the icon to log off.
	Indicates the status of the current print job: • When a print job is being sent, the icon is displayed. • When the print job has been sent, the icon is hidden.

Power Management

The system includes a power management feature to maximize the length of time that the system can operate on battery power. This feature also monitors the power level of the battery and notifies you when the system needs your attention. When you close the lid without turning off the system, the power management feature puts the system into a low-power portability mode to conserve battery power. Additionally, the power management feature can shut down the system before the battery loses power.

A fully charged battery typically powers the system for up to 40 minutes.

Battery and AC Indicators

The status of the battery and the AC adapter is indicated by icons on the system monitor.

Battery and AC Adapter Status Indicators

Icon	Description
	The system is running on AC power, and the battery is fully charged.
	The system is running on AC power, and the battery is charging.
	The system is running on battery power, and the battery is fully charged. Each band represents 20% of full battery power.
  	The system is running on battery power, and the battery is partially charged.
	The system is running on battery power, and the battery is nearly depleted and should be charged.

Changing Power Management Settings

In the setups, you can change the settings for portability mode and the battery level warnings.

1. Press the **Setup** key.
2. In the setups, click the **Power Management** tab.
3. Under **Portability Mode**, do either of the following:
   - To enable or disable portability mode, select or deselect **Portability Mode enabled when display lid is shut**.

- To set the interval between entering portability mode and the start of system shutdown, click  or  under **Time before transition to full shutdown (mins)** to set a time.

4. Under **Battery Level Warnings**, do either of the following:

   - To set when the low-battery warning is displayed, click  or  under **Time remaining at low battery warning (mins)** to set a time.
   - To set when the critical-battery warning is displayed, click  or  under **Time remaining at critical battery warning (mins)** to set a time.

5. Click **Apply**, and then click **Close**.

AC Adapter Operation

The AC adapter for your system provides power to the system while also charging the battery installed in the system.

The system receives its power from the adapter whenever it is connected to the system and is receiving AC power. The adapter also charges the battery in that situation, unless the battery is already fully charged. Battery charging occurs even when the system is turned off, if the adapter is connected to the system and to AC power.

WARNINGS

- Use only the AC adapter supplied with your system.
- When using the AC adapter and the system off the cart, do not place them on the floor or on a patient bed. Place them on a table or chair.

CAUTION

When disinfecting the AC adapter, do not spray it with disinfectant; instead, unplug the adapter and wipe it with disinfectant, being careful to avoid getting any liquid inside the adapter.

AC Adapter Indicator

The indicator on the AC adapter shows the mode of operation and alerts you if an error condition occurs.

AC Adapter States

Indicator State and Color	Condition
Steady amber	The AC adapter is powered but disconnected from the system.
Flashing green	The AC adapter is powered and connected to the system without a battery installed.
Steady green	The AC adapter is powered and connected to the system with a battery installed.
Flashing or steady red	The AC adapter is indicating an error condition. Contact your Philips representative if this condition persists for more than a few seconds. **NOTE** The indicator may flash red briefly when connecting or disconnecting the AC adapter or battery. This behavior does not indicate an error condition.

Using the AC Adapter

WARNINGS

- Connect the system only to a hospital-grade outlet.
- The AC adapter may become hot. Do not touch the surface of the adapter; touch only the adapter handle.

1. Connect the AC adapter to the power receptacle on the back of the system. The connector is designed to be inserted only in the correct orientation.
2. Connect the power cable of the AC adapter to a wall outlet.
3. To charge the battery, do one of the following:
   - To recharge while using the system, turn the system on.
   - To recharge when not using the system, leave the system off.

NOTE

For the fastest charge rate, turn the system off. When the system is on, the AC adapter charges the battery at a slower rate.

Battery Operation

For portable operation, the system is powered by an internal lithium polymer battery. To protect the battery and prolong its life, follow these guidelines.

WARNINGS

- Attempting to open the battery or incinerate it can result in serious injury. Do not strike, puncture, drop, or throw the battery.
- Do not immerse the battery in liquid or short the battery contacts with liquid or metal objects.
- Keep the battery clean and dry.
- Keep the battery out of the reach of children.
- If a battery case has been cracked, punctured, or otherwise compromised, place the battery in a heavy-duty resealable plastic bag, and dispose of it as hazardous material, in accordance with local, state, or federal laws.
- If a battery leaks or emits a strong odor, remove it from the system and store it away from any ignition source. Avoid contact with the fluid. If you get fluid on your skin, wash the area with copious amounts of water and seek medical assistance.
- If a damaged battery must be shipped, place the battery in a heavy-duty resealable plastic bag and ship it by ground as Class 9 hazardous material. Do not ship damaged batteries by air.
- Do not charge or store the battery in direct sunlight or high temperatures. For safe operating and storage temperatures, see "Environmental Requirements" on page 108.

CAUTIONS

- Do not operate the system at ambient temperatures below 10°C (50°F) or above 40°C (104°F).
- Use only batteries supplied by Philips in your system.
- Before using a battery for the first time, charge it in the system for one hour.
- Do not store batteries in direct sunlight or at ambient temperatures below -30°C (-22°F) or above 70°C (158°F).
- Recharge the battery immediately after use. Storing a discharged battery will damage its capacity. For storage, a battery should charged to at least 40% of capacity.
- Remove the battery from the system if it will not be used within two weeks.
- When shipping a system, remove the battery from the system and protect it against damage during shipping.

- The battery is sealed and is safe for normal use, provided that the operating instructions are observed and the battery case has not been compromised.
- For storage longer than six months, charge a battery to a level between 40% () and 60% ().
- The battery can be charged only when it is in the system.
- The battery can be safely cleaned using isopropyl alcohol (70% solution in water), mild soap and water, or Sporicidin disinfectant solution.

Installing the Battery

Use the following procedure to install or remove a system battery.

1. Turn off the system and wait for it to finish powering down.
2. Close the system lid and then turn the system over.
3. Press the latch on the battery cover and lift the cover up and away from the system.
4. Do one of the following:

- To remove the battery, grip the battery handle and, lifting the connector side of the battery first, pull the battery out of the compartment.
- To install the battery, lower the side of the battery opposite the connector into the compartment, and then push the connector side into the compartment.

5. Replace the cover, ensuring that it latches securely.

Battery Installation

Lifting the cover	
Installing the battery	

System Security

The data security feature, if implemented on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log on to the system using a password. When you are finished using the system, you can log off manually or simply shut down the system, which logs you off automatically. If the automatic log-off function is enabled, you are logged off automatically after the system has been inactive for a predefined length of time, which is set by the system administrator. The system can be configured to end the current study upon automatic logoff. Only the system administrator can change the password.

The data security feature is set up by your system administrator. For more information, refer to "System Administration" in Help. To display Help, press the **Help** key.

Logging On to the System

When data security is enabled, you must log on to the system before you can view or load patient files or start a new study.

1. Do one of the following:
   - If you are beginning a study, press the **Patient** key.
   - If the system has automatically logged you off, press **Review** and then click  .
2. For **Password**, type your password and click **OK**.

Logging Off of the System

If you do not log off manually, the system will automatically log you off when you shut down the system. If the automatic log-off function is enabled, you are logged off automatically after the system has been inactive for a predetermined length of time. Logging off of the system does not change the current patient, but it does deny further access to protected patient data.

1. Press the **Review** key.
2. Click  .
3. Click **OK** to log off, or click **Cancel** to remain logged on.

Temporary ID

In an emergency, use the temporary ID feature to start a study quickly. This feature allows you to log on without a password and perform a study without first entering patient data. When you select this feature, the system enters unique, temporary placeholders for the patient's last name and ID. Using the temporary ID feature allows you to perform a study as you would normally, except that access to prior patient data is not available if the data security feature is implemented.

NOTE

If another study is active when you use the temporary ID feature, the active study is saved and closed without notification.

Patient data can be entered at the end of the study or later, depending on export configuration:

- If the system is configured for batch export, you must enter patient data before ending the study.
- If the system is configured for manual export, you can enter patient data up to 24 hours after the study is ended.

Images can be printed before entering patient data, if the system is configured to print images as you scan, but those images are labeled only with the temporary ID.

Starting Emergency Studies

In an emergency, you can use the temporary ID feature to start a study without having to first enter a password and patient data.

1. Do one of the following:

- If no study is active, press **Acquire**, and then click **Temporary ID**.
- If a study is active, press the **Patient** key, and then click **Temporary ID**.

2. When the study is finished, press the **Patient** key, click **Edit**, and edit the emergency patient data.

NOTE

In studies with a temporary ID, you cannot edit patient data after acquiring an image if your system is configured to automatically export images. If your system is configured for manual export, you can enter patient information up to 24 hours after the study is ended.

System and Data Security

Because of its size, the system is an easy target for theft if it is not secured. When the system is not being used, secure it using a standard laptop cable lock.

Follow the instructions included with the cable lock to secure the system to an immovable object. A Kensington lock receiver is on the left side of the system, near the rear.

Kensington Lock Receiver

Because system theft could expose patient health information, export patient data and images regularly to removable media or to a DICOM-compatible device on a network. After exporting such data, delete it from the system.

Imaging Display

The imaging display contains an ultrasound image, study and image information, quick key labels, and indicators.

The image area is approximately in the center of the display. The image area includes scales indicating the depth and focus settings, curves representing the TGC and LGC settings, a color or grayscale bar, and, in M-Mode and Doppler, the sweeping display.

The study information includes the patient data, the current time and date, the institution name, and the TI and MI values. The system does not display patient data until you start a study. You can use the **Hide ID** key to prevent the system from displaying the patient data in the exam information. The TI values appear as TIS, TIB, or TIC, depending on the selection for **Thermal Index** in the system

setups. Each application provides a default TI display that is used when the **Thermal Index** selection is **Normal**.

Image information is displayed to the left of the image. This includes the transducer and preset in use. At the bottom of this area, icons indicating active features appear. These icons include active imaging features, printer status, and acquire states.

The imaging display size can be adjusted in the system setups.

The quick key labels appear along the bottom of the display.

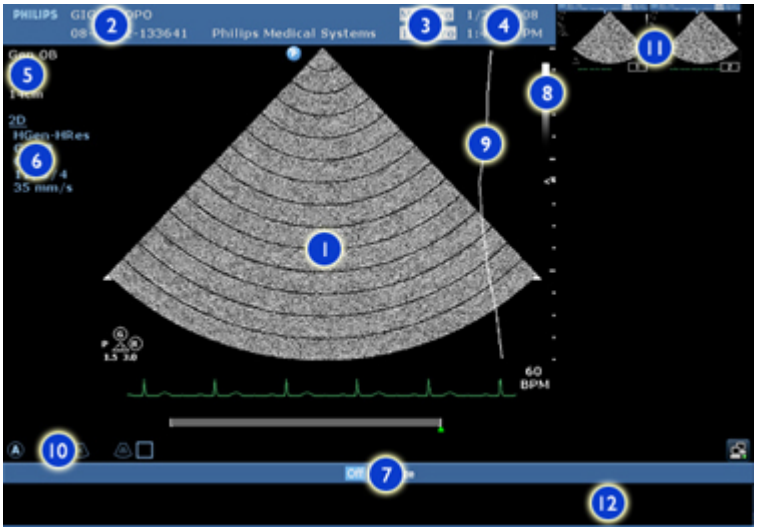
	Description	Imaging Display
1.	Imaging area	
2.	Patient and study information	
3.	MI and TI values	
4.	Time and date	
5.	Preset and transducer	
6.	Imaging settings	
7.	Select menu	
8.	Grayscale or color bar	
9.	TGC curve	
10.	Status icons	
11.	Thumbnail images	
12.	Quick key labels	

Image Size Settings

The **System** setups include an option to set the image area size on the display. The default setting, **Medium**, fits the image area to include 100% of the display area. You can adjust this to use slightly more (**Large**) of the display area.

This setting does not affect the 2D reference image size in M-mode or Doppler imaging when the spectral trace is also displayed. Also, it does not affect the image size in dual or comparison images.

Transducer Use

The system includes one receptacle for an imaging transducer and one receptacle for a pulsed- or continuous-wave Doppler probe. Both receptacles can be occupied simultaneously, but only one transducer at a time can be active.

When using the system on the optional cart, follow these guidelines:

- When a transducer is not in use, store it in one of the transducer holders on the system cart.
- Always use the cable management system to prevent cables from being stepped on or run over by the cart wheels.

For more information, see the section.

Connecting Transducers

The system has one imaging transducer receptacle and one Doppler probe receptacle. Both receptacles are located on the right side of the system.

- To connect an imaging transducer, insert its connector fully into the receptacle and move the locking lever up.
- To connect a Doppler probe, insert its connector into the receptacle until it latches.

Connecting a Transducer

Selecting a Transducer

If an imaging transducer and a Doppler probe are connected when the system is turned on, the system defaults to the imaging transducer. During system operation, you can select between the imaging transducer and the Doppler probe. When you connect a transducer to the system, it is selected automatically.

You can disconnect a transducer or connect a new one during live imaging without damaging the transducer or the system.

Press **Transdcr** to select a transducer or probe. The selected transducer is indicated on the display.

Selecting a Preset

During system operation, you can select a clinical option preset for the selected transducer. For more information on presets, see "Presets" on page 147.

1. Press **Preset**.
2. On the **Presets** menu, select a preset.

Using Presets

These tips can help you understand presets and use them effectively.

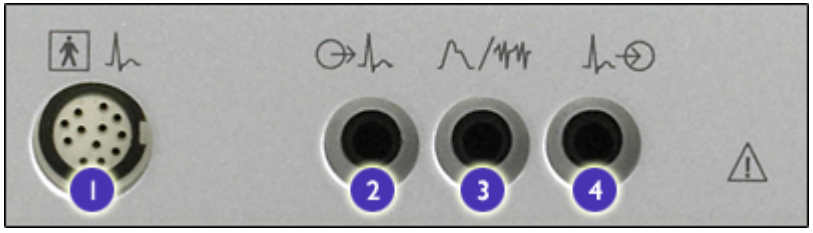
- When a study moves to another part of the anatomy, you can select a different preset that is appropriate for that application.
- If you want to return the system to the default settings of the current preset, either with the current transducer or after selecting a different one, simply select the current preset again.
- If you select a different transducer that is compatible with the current preset, that preset remains selected and any setting changes you made remain in effect.
- When you select a different transducer that is not compatible with the current preset, the system selects a compatible preset. This can be either the system

default for that transducer or the preset that you selected for it using **Autoselect** in the setups.

Physio Feature

The system can display three physio traces, each representing a physiological input. Those inputs can include low-level ECG, high-level ECG, respiration, pulse, phono, and auxiliary signals. (Low-level ECG comes from leads connected to the patient; high-level ECG comes from a patient monitor or other similar equipment.) Heart rate, derived from the ECG signal, is displayed whenever ECG is connected and displayed.

Physio Receptacles

	Description	Physio Panel
1.	Low-level ECG input	
2.	Analog output	
3.	Pulse/Phono/Aux 2 input	
4.	External ECG/Aux 1 input	

For information on using ECG, see Help on the system. To display Help, press the **Help** key.

DVD and USB Devices

Removable media compatible with the system include DVD, CD, and USB storage devices.

The system includes a DVD drive on the left side of the system. You can use this drive to store and transfer patient files, including full studies and reports. Also, you can save, restore, and distribute setups data, including presets.

You do not need to format a disc before storing data on it. For this reason, the format function is not enabled for discs.

For additional information on specific applications of the DVD drive, refer to Help on the system. To display Help, press the **Help** key.

Media Compatibility

DVD and CD media are available in a number of types. Not all media types are fully compatible with the system DVD drive.

Media

CD media capacity is approximately 700 MB; DVD media capacity is approximately 4.7 GB. DVD+RW media can be erased and used again, but DVD+R and CD-R media cannot be erased.

Multiple studies can be written to a disc, up to the limit of its capacity. This includes moving a single DVD or CD between different CX50 Ultrasound Systems and writing studies from each system to the disc.

Compatible Media

The following disc types can be used in the system DVD drive:

- CD-R
- DVD-R
- DVD+R
- DVD+RW

NOTE

DVD-RWs and CD-RWs have slow write speeds, making them unsuitable for use in the system DVD drive.

Loading and Ejecting a Disc

Do one of the following:

- To eject a disc, press the Eject button on the drive.
- To load a disc, gently guide a disc into the drive slot until the disc is pulled into the drive.

USB Devices

The system provides USB ports that can be used to connect USB storage devices. Such devices include USB memory devices and USB hard disk drives. USB ports are on the right side of the system. Read the following information before using USB storage devices.

WARNING

Connecting externally powered USB hard disk drives to the system involves electrical safety risks. If you connect such drives to the system, you must observe the electrical safety warnings in "Safety". Philips recommends that you use only USB hard disk drives powered from the USB connector, or use USB memory devices.

CAUTIONS

- When transferring data to or from a USB device, be sure the transfer is complete before removing the USB device. For USB devices that have an indicator, be sure the indicator is no longer flashing before removing the device.
- Ultrasound systems may become vulnerable to security breaches when they accept removable media. Removable USB storage devices may contain viruses. Philips recommends that you use the system to format USB storage devices before working with them. USB storage devices are easily lost or damaged. Philips does not recommend that you use USB storage devices for long-term storage. Follow your IT department's recommended practices for intended use of USB storage devices. For more information about security on the ultrasound system, see *Shared Roles for System and Data Security*, included on your User Information CD.
- If the system encounters issues when you connect a U3 smart USB flash memory drive (for example, a U3 or SanDisk Cruzer Titanium drive), remove it from the system and discontinue use of that type of USB device.
- Use only Class-B-compliant USB storage devices with the system. USB devices that are not Class-B compliant may cause RF emissions that exceed Class B limits. See the device's documentation to determine whether it is Class-B compliant.

NOTES

- The USB ports on the system cart are intended to support only approved printers and a foot switch. Do not connect a USB flash drive or a portable hard drive to the USB ports on the cart.
- A portable hard drive is available for use with the system. It connects to the system through a dual-port USB cable, providing both power and data connections. This hard drive cannot be used with USB ports on the system cart, which do not provide the needed power.

Erasing a DVD or USB Device

Erasing a rewriteable disc (DVD+RW or CD-RW) or USB device erases all data on it and prepares it for reuse. After a disc or USB device is erased, the entire capacity of the disc or device is again available. You can also erase a write-once disc (DVD+R, DVD-R, or CD-R) , but you will be unable to write files to the erased portion of the disc.

CAUTION

You cannot restore data after it is erased from a disc or USB device.

1. Load the disc into the drive, or connect the USB device to a USB port on the system.
2. Press **Setup**.
3. Click the **Removable Media** tab.
4. In the **Select Media** menu, select the DVD drive or USB device.
5. To see the contents of the disc or device before erasing, click **Browse Media**.
6. Click **Erase Media**.
7. In the **Erase Media** dialog box, click **Yes** to erase.
8. When the dialog box indicates that erasing is complete, click **OK**.
9. Click **Close**.

Formatting a USB Device

Some older USB devices may need to be formatted before you can use them on the system. Formatting a USB device erases all data on it and prepares it for reuse. After a USB device is formatted, the entire capacity of the device is again available.

CAUTION

You cannot restore data after it is erased from a disc or USB device.

1. Connect the USB device to a USB port on the system.
2. Press **Setup**.

3. Click the **Removable Media** tab.
4. In the **Select Media** menu, select the USB device.
5. To see the contents of the device before formatting, click **Browse Media**.
6. Click **Format Media**.
7. In the **Format Media** dialog box, click **Start**.
8. Click **OK** to format.
9. When the dialog box indicates that formatting is complete, click **OK**.
10. Click **Close**.

6 *Customizing the System*

You can customize your system to increase efficiency and streamline your workflow. You can do the following:

- Create presets designed specifically for the exams you perform
- Change system settings to reflect your needs
- Add options to enhance your imaging abilities

Presets

A preset is a group of settings that optimizes the system for a specific type of exam. Presets establish many initial imaging settings, such as gain value, color map, filter, and which quick keys, annotations, and body markers are available.

When the system is turned on, the system selects the same preset that was in use when the system shut down, unless it is incompatible with the initially selected transducer. In this case, the system activates the autoselect preset for that transducer.

In addition to the presets provided with the clinical options, the system lets you create and use custom presets.

NOTE

Presets are available only if you purchased a corresponding clinical option.

Clinical Options and Predefined Presets

Clinical options are broad areas of medical study. Within each clinical option, there are predefined presets for specific areas of study. The **Preset** menu is used to select among the available presets for the selected transducer.

You specify how the imaging parameters and certain related functions will be set up by selecting a preset. The more specific you are about your intended use of the system, the more you can benefit from presets.

Custom Presets

Custom presets provide a quick way to set imaging parameters to the values you prefer for a specific exam type. Using the custom preset feature, you can define presets for specific clinical options and transducers. A custom preset stores the imaging settings that are active when you create the custom preset.

A custom preset can include certain settings found in the setups. Settings that affect the imaging display or imaging functions can be saved in a custom preset. For example, you could change the gain and set the number of focal zones, and then save these changes to a custom preset. Neither factory presets nor custom presets store settings that affect the system as a whole, such as date and time, system options, and DICOM settings.

A custom preset is based on the factory preset or custom preset that is active when you create the custom preset. Thus, the custom preset will be compatible with the same set of transducers as the active preset. After you create a custom preset, it appears as an item on the **Preset** menu if a compatible transducer is active. When you select the custom preset, the system automatically invokes the settings in the preset. You can modify or delete existing custom presets, copy them onto a DVD or USB device, and load them into another system.

Creating Custom Presets

You can create a custom preset that is based on an existing preset. You can do this even during a study, while using the preset.

1. Press **Preset**.
2. On the **Preset** menu, click the preset on which you want to base your custom preset.
3. Adjust the imaging controls to create the settings for your preset. You can select an imaging mode, change the gain, set the number of focal zones, and so on.
4. To include changes made in the setups to a custom preset, do the following:
   a. Press the **Setup** key.

b. Make changes to settings that affect the imaging display or imaging functions.
c. Click **Apply**, and then click **Close**.

5. Press **Preset**.
6. Press **Save Preset**.
7. In the **Save Preset** dialog box, click **Create New**.
8. In the **Create New Preset** dialog box, type a name for the new preset.
9. Click **Save**.

Modifying Custom Presets

You can modify existing custom presets and save your changes. You can do this even during a study, while using the preset.

1. Press **Preset**.
2. On the **Preset** menu, click the custom preset you want to modify.
3. Adjust the imaging controls. You can select an imaging mode, change the gain, set the number of focal zones, and so on.
4. To include changes made in the setups into a custom preset, do the following:
   a. Press the **Setup** key.
   b. Make changes to settings that affect the imaging display or imaging functions.
   c. Click **Apply**, and then click **Close**.
5. Press **Preset**.
6. Press **Save Preset**.
7. In the **Save Preset** dialog box, click **Modify Current**.
8. If you want to change the name of the existing preset, change it in the **Modify Current Preset** dialog box and click **OK**.

Deleting Custom Presets

You can delete any custom presets on the system, including the current preset. Factory defaults cannot be deleted, but you can hide them on the **Preset** menu.

1. Press **Preset**.
2. Move the cursor over the preset you want to delete.
3. Press **Delete Preset**.
4. In the **Delete Preset** dialog box, click **OK**.

Presets Menu

The **Presets** menu can display items in two ways: **Show All** or **Show Exam Type**.

- In **Show All**, the **Presets** menu contains a list with exam types and presets together, with presets indented under the relevant exam type.
- In **Show Exam Type**, the **Presets** menu contains either the presets in a single exam type or a list of exam types.

When you press **Preset**, the system shows the menu in the state in which it last appeared.

In the setups, presets available with a specific transducer are designated either primary or secondary for that transducer. By default, the **Presets** menu shows only the primary presets. Clicking the **More** item in the menu displays all presets for the current transducer.

Using the Presets Menu

Press **Preset** and do any of the following:

- Click **Show Exam Type** to show the presets in a single exam type.
- Click the exam type to display only the available exam types without the presets.
- Click **Show All** to show all exam types and their associated presets.
- Click **More** to display both the primary presets and the secondary presets for the current transducer.

Modifying the Presets Menu

In the setups, you can select which presets appear in the **Presets** menu, change the order of the presets, and assign which preset will be automatically selected when a transducer is selected and the current preset is incompatible with the selected transducer.

1. Press the **Setup** key.
2. Click the **Preset Menu** tab.
3. Highlight a transducer in the **Supported Transducer** list.
4. In the **Preset Menu** list, do any of the following:
   - To change the location of a preset in the **Preset** menu, highlight it and click **Move Up** or **Move Down**.
   - To change the location of an exam type and its presets, highlight the exam and click **Move Up** or **Move Down**.
   - To make a preset secondary, so that it is hidden in the default **Preset** menu, deselect it (the check mark disappears).
   - To make a preset primary, so that it is included in the default **Preset** menu, select it (the check mark appears).
5. To set a preset as the one to be automatically selected when the current preset is incompatible with the selected transducer, highlight the preset and click **Assign Autoselect**.
6. To reset all settings in the **Preset Menu** tab to factory-provided default values, click **Clear Preferences** and do one of the following:
   - To reset preferences for all transducers, click **All**.
   - To reset preferences for only the transducer that is highlighted in the **Supported Transducer** list, click **Current**.
7. To save your changes, click **Apply**.
8. Click **Close**.

Copying Custom Presets

You can copy custom presets and **Presets** menu modifications to a DVD or a USB device. This function is useful for archiving presets and for sharing presets among other CX50 systems. For more information on copying custom presets to and from removable media, see the "System Administration" section in the Help.

System Setups

Setups provide control over system parameters that you can change. In the setups, you can customize the system to meet your operating preferences. The setups are organized into categories by tabs located along the top of the **Setup** display. Most changes in the setups take effect when you apply or save the changes. Some changes, however, take effect when you click **OK** in a dialog box within the **Setup** dialog box; examples include the settings in the **Dual** and **Date/Time** dialog boxes.

There are two types of information controlled by the setups:

- System information can be applied but cannot be saved to presets. Changes applied to this type of information remain in effect until you change them again or load setup information from a DVD or USB device. These changes remain in effect even after the system has been turned off and on again.
- Preset information can be applied to the current study or can be saved to custom presets. Changes *applied* to this type of information remain in effect until you change them again, start a new study, or load setup information from a DVD or USB device. Changes to this type of information *saved* to a custom preset remain in effect until you change them again, switch to another preset, or load custom presets from a DVD or USB device. Preset information is updated each time you switch to another preset.

NOTE

The institution name exported with DICOM data always reflects the name shown in the setups at the time the study ended. When you change the institution name in the setups, Philips recommends restarting the system after changing the institution name.

For information on individual setup options not described elsewhere, see the "Glossary" section in the Help.

Changing Setups

1. Press the **Setup** key.
2. Click a tab to select a setup category.
3. Enter text or make selections necessary to set up your system.
4. To apply your changes to system or preset information types, do one of the following:
   - To apply changes to system information, click **Apply**.
   - To apply changes to preset information for this study only, click **Apply**.
5. To save your changes to preset information, click **Save** and then do one of the following:
   - To save changes to the current custom preset, click **Modify Current**.
   - To save your changes to a new custom preset, click **Create New**, type a name for the preset, and click **Save**.

Options

In addition to the standard features available in the system, other features are available as purchasable licensed options. The types of options available include clinical options, imaging capabilities, QLAB Advanced Quantification Software plug-ins, and connectivity capabilities.

For a list of options available for your system, see "System Options" on page 76.

Installing Temporary Options

The system lets you temporarily install licensed options. You can then evaluate these options for a fixed length of time, which is set by Philips. Before you can install temporary options, you must request and receive an access code for each option you want to install. The installation process requires restarting the system, so be sure that the last study has been closed before installing options.

1. Press the **Setup** key and click the **Options** tab.
2. In the **Options** display, click **Options** and note the names of the options you want to install.
3. Contact your Philips representative and request an access code for each option you want to install.
4. When you receive your access codes, display the options list as described in step 1 and step 2 .
5. In the options list, select an option to install.
6. Click **Install**.
7. In the **Access Code Required** dialog box, type the access code for the option you selected, and then click **OK**.
8. To install additional options, repeat step 5 through step 7.
9. To complete installation, click **OK** and then click **Close**.
10. Turn the system off, and when it has fully shut down, turn it on again. The temporary options you installed are now available.

7 *Performing a Study*

This section guides you through procedures commonly used in performing patient studies with the system. These procedures include entering patient data; acquiring, annotating, and reviewing images; and making measurements and calculations.

For detailed information on the controls, features, and tasks mentioned here, see Help. To display Help, press the **Help** key.

New Patient Studies

You must create or restart a patient study before you begin acquiring images. If you do not, you cannot acquire, print, or save images. The way you create a patient study depends on whether you are using the Modality Worklist feature.

WARNING

Failing to end the current study before starting a new study can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the study, the system automatically ends the study before shutting down.

You start a study by entering patient data into the system. (But you can also create a study with a temporary ID without first entering patient data). There are two ways to enter patient data.

- If the worklist feature is not enabled or used on your system, you enter patient data into the **Patient Identification** display.
- If your system is connected to a DICOM network with the Modality Worklist feature enabled, you can select a study from the **Patient Selection** display to load patient data instead of entering that information manually.

The system uses a unique medical record number (MRN) to identify each patient. You can enter an MRN, or you can have the system create one

automatically. Stored images and reports are stored based on the MRN. An accession number is an optional entry that an institution can assign to each patient file, for internal information-management purposes.

The system sets the study date when you first acquire an image during the study.

Entering Patient Data Manually (Without Worklist)

If you are not using the worklist option, you start a study by entering patient data into the system.

NOTE

Before entering patient data, verify that the date and time displayed on the system are accurate.

1. Ensure that the previous study ended by pressing the **End Exam** key or by clicking  in **Review**.
2. Press the **Patient** key.
3. In the **Patient Identification** display, click **New**.
4. In the **Patient Identification** display, type the patient information. (Press the **Tab** key to move the cursor from field to field.)

NOTES

- If you enter a last name, but not an MRN, the system automatically generates an MRN based on the current time and date. Philips recommends that you enter the MRN.
- The same MRN is used for a single patient folder.
- If you create two studies with different patient names but with the same MRN, the system prompts you to enter a new MRN or to use the same MRN and change the patient name.

5. Click the **Additional** tab.
6. For **Additional Data Types**, select the study you will be performing.
7. Enter the pertinent study information for the patient.

8. When you are finished, click **OK**.

Using Modality Worklist

Before you use Modality Worklist, you must specify the Modality Worklist server. Modality Worklist is a component of the DICOM Networking option.

1. Press the **Patient** key to open the **Patient Selection** display. The **Modality Worklist** displays scheduled patients.
2. In the **Patient Selection** display, click a column header to sort the worklist by last name, exam time, or another category.
3. Search for the patient, if necessary:
   - Enter one or more letters or numbers in the **Find** field, and select a column from the **In Column** menu. As you type, the list changes to show only the patients that match your criteria.
   - To find a subset of the results, type a value for a different column in the **And** field, and select the column from the **In Column** menu.
   - To store the current filter settings as the default, click **Save Filter**.
   - To start a new search, click **Clear Filter**.
4. Do one of the following:
   - Select the patient. Click the name of the patient and click **OK**, or double-click the highlighted patient name. The **Patient Identification** display opens and is populated with the patient's information. You can edit and save.
   - If the patient's name does not appear in the **Patient Selection** display, click **Manual Entry** to open a blank **Patient Identification** display.

Selecting a Transducer

If an imaging transducer and a Doppler probe are connected when the system is turned on, the system defaults to the imaging transducer. During system

operation, you can select between the imaging transducer and the Doppler probe. When you connect a transducer to the system, it is selected automatically.

You can disconnect a transducer or connect a new one during live imaging without damaging the transducer or the system.

Press **Transdcr** to select a transducer or probe. The selected transducer is indicated on the display.

Imaging Modes

Your ultrasound system offers a set of imaging modes to accommodate a variety of imaging applications. Some modes display a live grayscale image. Others are Doppler modes to evaluate the amplitude or the direction of the blood flow and the spectral information.

NOTE

Some modes are available on your system only if the corresponding option has been purchased and installed.

Using 2D Mode

NOTES

- With sector transducers, the top of the image does not correspond to the skin line.
- The color and state of the backlight on the controls and their labels indicates the status of controls and modes. When a control's backlight is amber, the control is available but inactive. When the control's backlight is green, the control is active. For multi-use controls, such as **Depth**/**Focus**, press the control to change the active function.

1. Press **2D** to start 2D imaging, if necessary.(The system turns on in 2D mode, unless a CW probe is the only transducer connected.)
2. Optimize the image using any of the following methods:

- To automatically optimize the TGC and gain settings for the current image, press **iSCAN**.
- To control the image brightness, adjust the **Gain**.
- To increase or decrease the distance from the face of the transducer to the deepest point in the displayed image , use **Depth**.
- To select the area where the image will be most clearly focused, adjust **Focus**.
- To optimize the transmit and receive frequencies and penetration and resolution for the image, use **2D Opt**.
- To compensate for signal attenuation, use the **TGC** and **LGC** controls. Use **TGC** to increase or decrease the amplification of the signal to adjust the brightness of the image at different depths, and use **LGC** to adjust the amplification at the edges of the sector. You can use the **TGC** and **LGC** controls during live imaging, after freezing the image, or post-acquisition from the Quick Review buffer.

3. To enter another imaging modes, press the control for that imaging mode.
4. To return to 2D-only imaging from any other imaging mode, press **2D**.

Annotation

You can place text labels and arrows on an image to identify anatomical structures and locations. You can also annotate an image with a body marker graphic that indicates the part of the anatomy that you are scanning.

NOTE

You can add, modify, or delete annotation labels and body markers on an image in Review only if the image contains active native data. Changes to annotation labels and body markers in Review are not retained with the image unless you acquire the image in Review.

Placing a System-Defined Label on the Display

You can place system-defined labels on the display by pressing **Text**.

1. Press **Text**.
2. Do any of the following:
   - Position the cursor where you want the label to appear and press the **Lt/Mid/Rt** or **Long/Trans** quick key until the label you want appears on the display.
   - Press the **Lt/Mid/Rt** or **Long/Trans** quick key until the label you want appears on the display. Click the label and drag it to the position you want it to appear.
   - Position the cursor where you want the label to appear, turn **Menu On**, and move the trackball to scroll through the menu selections on the display. Click **Enter** or press either trackball button to anchor the label you want on the display.

NOTE

You can also turn the knob beneath the **Menu** quick key to scroll through the menu selections on the display.

3. Press **Text** to exit.

Typing a Label on the Display

Do one of the following:

- Use the four arrow keys (**PgUp**, **PgDn**, **Home**, and **End**) to position the cursor on the display, and then start typing. If you do not position the cursor, the cursor appears at the home position. Press the left trackball button to exit.
- Press **Text**, position the cursor where you want the label, type the label, and press **Text** to exit. (Press the **Home** quick key to add text at the home position.)

Placing a Body Marker on the Display

Body marker sets are organized by exam type.

Do one of the following:

- Press **Marker**, and then turn the quick key to the left of and below the **View All** quick key until the set of body markers that you want appears. Turn the quick key on the far left until the body marker that you want appears. Click the marker and drag it to the desired location on the display, and then press **Enter**.
- Press **Marker**, and turn **View All On**. In the **Select Body Marker** dialog box, click the tab for the desired exam type, and click the body marker you want.

Printing

You can print single-frame images and reports to a local printer, usually inside the system, or to DICOM printers on a network. The printer can be a color printer, a black-and-white printer, or a report printer.

The **Print** control is available for printing images. The **Acquire** control also has print capabilities associated with it.

In the setups, you can assign those controls separately to image printers. **Print** and **Acquire** can print to local and network printers. Report printing is assigned to a single dedicated report printer.

Review

During or after a study, you can use Review to examine and compare still-frame images and loops acquired in the study. You can view images, delete images from the study, edit loops, and end the study. You can also edit Stress Echo loops, specify the preferred Stress Echo loop, and relabel Stress Echo views.

You can export images and studies from Review to a CD, a DVD, a USB removable-storage device, or DICOM-compatible devices on a network.

You can make measurements and annotations in the image view. Measurements made in Review on the current study can be saved in the report. Measurements made in Review on prior studies cannot be saved.

NOTE

You can hide measurements and calculations in Review by pressing the **Hide Measurements** quick key.

If your image supports active native data, the system saves raw image data with the image, which enables you to perform most of the same adjustments to an image in Review as you can in live imaging.

Use Compare in Review to compare live images with previously acquired images.

Starting Review

1. Press the **Review** key.
2. To return to live imaging, press the **Review** key again, or press **2D**.

Navigating Thumbnails and Images

In Review, you can switch between thumbnail view and image view.

1. To switch to thumbnail view from full-screen image view, click  .
2. To switch to full-screen image or loop from thumbnail view, double-click the thumbnail image, or click the thumbnail image and then click **Play**.

NOTE

If you have selected an *n*-up option from the **Image Selection** menu, *n* number of images or loops appear when you enter image view.

3. To view a different thumbnail as a full-screen image or loop in image view, do one of the following:
   - Double-click the thumbnail.
   - Turn **Page**. For example, turn **Page** to **3** to view the third thumbnail.

Acquiring Images and Loops

NOTES

- Acquisition during live imaging saves prospective or retrospective frames, as specified in in the **Acquisition** settings. Acquisition while reviewing a cineloop sequence saves all frames within the start and end markers in the cineloop sequence.
- When you acquire an image, the system beeps to confirm that acquisition is complete, if you have selected **Beep After Acquire Completes** in your **Acquisition** setups. When the image is saved to the patient study, a thumbnail appears. Do not press **Review** until you see the thumbnail of the acquisition.
- When the **Acquisition** setting **Accept Prior to Store** is selected, you have the option of accepting or rejecting the acquisition after pressing **Acquire**.
- During an acquisition, the icon appears as  . **Acquire** is inactive when this icon appears. You must wait for the ready to acquire icon  to appear.

You can acquire and save a single frame or a cineloop sequence. The frame or cineloop sequence is saved in the patient study, and a thumbnail of it is available in the live imaging display and the Review display.

When the acquisition is complete, a thumbnail of the image is displayed.

- To acquire a single image, press **Freeze** and then press **Acquire**.
- To acquire a cineloop sequence, press **Acquire** in live imaging or while reviewing a cineloop sequence.

Measurement and Analysis

The ultrasound system supports a number of measurement and quantification methods. The basic measurements report the size, speed, or duration of image data. The image data may be contained in a 2D ultrasound image, a Physio region, an M-mode trace, or a Doppler spectral trace. The accuracy of the measurement depends, in part, on the ability of the operator.

Measurements require scaling information. This prevents measurements in instances where Doppler or M-mode still images in Review do not include scaling information in the trace data or where imported image loops use a different scaling parameters.

There are two basic methods for quantifying the image data for reporting. You can "measure then label," using the **Caliper** and **Trace** tools and then associating the measurement with a calculation label. You can also "label then measure," using the analysis tools to select a labeled measurement. Measurements must be labeled for the results to appear in patient reports. Unlabeled and primitive measurements appear in the results but are not retained, unless they are associated with a labeled measurement.

Calculations packages are system options that are associated with transducers and presets. A calculations package contains one or more collections that organize measurements and calculations into a coherent tool for diagnostic analysis. The **Calc** control provides access to the various measurements and calculations in the available calculations packages.

Labeled measurements and calculations are stored in the patient data and report. The information is labeled according to the measurement or calculation label. Within the report, the information is organized by the calculations package. The values displayed can be the results of multiple measurements. The report displays the method used to select the viewable result; this could be minimum, maximum, or average. You can also select a specific instance of the measurement using the **Use in Calcs** option. You can also edit the data in the report.

Analysis configuration in the setups allows you to create your own analysis menu lists. In addition, the measurements and calculations can be associated with system and custom tables and equations.

The measurements and their derived calculations included with the calculations packages are based on medical references. See "References" in Help.

NOTE

Ensure that you follow current medical practices when identifying specific measurement points on an image.

Performing a 2D Distance Measurement

A 2D distance measurement uses two calipers to measure the length of a straight line between the two points. You can set the display of the line in the **Tools & Results** setups.

NOTE

The trackball buttons can be set to one of three measurement operations: **End Measurement**, **Toggle**, or **Next Measurement**.

1. Obtain the 2D image you want to measure and press **Freeze**.
2. Press **Caliper**.
3. Use the trackball to position the caliper at the first point of the measurement.
4. Click to anchor the first caliper and display the second caliper.
5. Use the trackball to position the second caliper at the second point of the measurement. The results update as the distance between the calipers changes.
6. To end the measurement, click **Enter**.

Obtaining a Typical Labeled Measurement

This general procedure describes how to measure by using a typical labeled measurement tool. Guided or complex tools require specialized procedures, found elsewhere in the Help.

1. Obtain the image you want to measure and press **Freeze**.
2. Press **Calc**.
3. Do one or more of the following:
   - Select an analysis collection to display calculation and measurement labels. For more information on selecting a collection, see *Help*.
   - Select the calculation label you want to use to display the measurement labels required to complete the calculation. For each measurement label within a group, select a label and make the measurement.

- Select the label for the calculation or measurement you want to make to display the caliper or trace tool. As you make the measurement, the results and derived calculations appear in the results and are simultaneously added to the patient report.

4. Press **Enter** to complete the measurement.

Obtaining a Calculation Result

Calculations use two or more measurements. The required measurements are grouped under the calculation. If a measurement has already been made, the measurement label is marked with a check mark.

1. Obtain the image you want to measure and press **Freeze**.
2. Press **Calc.**
3. Select the calculation you want to add.The measurements required for the calculation appear in a menu.
4. Select and make each measurement.

Ending a Study

Each time you finish a study, you must end the study to save images, reports, and other study data.

Ending a study stores all study data, clears the **Patient Identification** display, and prepares the system for the next study.

WARNING

Failing to end the current study before starting a new study can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the study, the system automatically ends the study before shutting down.

When the study is complete, do either of the following:

- Press the **End Exam** key.

- Press the **Review** key, and then click  .

NOTE

If you've configured a modality performed procedure step (MPPS) server, or if you have configured the system to print all images at the end of the study, the system prompts you to either end or cancel the study when you press the **End Exam** key or click  in Review.

8 *Transducers*

The transducer that you select is the most important factor in image quality. Optimal imaging cannot be obtained without the correct transducer. The system is optimized for use based on your transducer selection.

The system limits patient contact temperature to 43 degrees Celsius, and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive current to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

It is important to understand how to connect, disconnect, and select transducers, and how to use the cable management on the system cart.

The system includes a receptacle for an imaging transducer and a receptacle for a pulsed- or continuous-wave Doppler probe. Both receptacles can be occupied at the same time, but only one transducer at a time can be active. On the optional cart, when a transducer is not in use, store it in one of the transducer holders on the system cart. When a transducer is not connected, put the connector cover on the connector and store the connector in one of the holders on the back of the cart. Always use the cable management system on the optional cart to prevent cables from being stepped on or run over by the cart wheels.

Selecting a Transducer

If an imaging transducer and a Doppler probe are connected when the system is turned on, the system defaults to the imaging transducer. During system operation, you can select between the imaging transducer and the Doppler probe. When you connect a transducer to the system, it is selected automatically.

You can disconnect a transducer or connect a new one during live imaging without damaging the transducer or the system.

Press **Transdcr** to select a transducer or probe. The selected transducer is indicated on the display.

Clinical Options and Transducers

The clinical options, or applications, for each transducer available for the system are listed here.

System Transducers and Supported Clinical Options

Transducer	Clinical Options
S5-1	Adult Echo
X7-2t	Adult Echo
D2cwc	Adult Echo

Transducer Care

Transducers require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization, as necessary.

For all information on transducer cleaning and disinfection and the use of acoustic coupling gels, see the "Transducer Care" section.

Acoustic Artifacts

The transducer adds its own signature to the echo information in the form of beam width effects, axial resolution limitations, and frequency characteristics. The control choices made by the sonographer that affect amplification, signal processing, and echo signal display can lead to significant differences in the displayed appearance of echo data. Following is a brief discussion of acoustic artifacts. An understanding of the physical basis for the production of signals

displayed on ultrasound images is helpful in minimizing artifacts on images and interpreting the results of studies.

An artifact is an echo displayed in a different position than its corresponding reflector in the body. Artifacts can also be caused by intervening tissue properties. Artifacts can originate from external noise, reverberations, multi-path reflections, or misadjusted equipment. They can also come from the ultrasonic beam geometry and unusual changes in beam intensity. Artifacts and their manifestations are listed below, and following are some definitions of various artifacts.

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, or ring down
- Missing objects due to poor resolution
- Incorrect object brightness due to shadowing or enhancement
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes, speed error, or range ambiguity
- Incorrect object size due to poor resolution, refraction, or speed error
- Incorrect object shape due to poor resolution, refraction, or speed error

Acoustic saturation occurs when received signals reach a system's high-amplitude limit. At that point the system becomes unable to distinguish or display signal intensities. At the point of saturation, increased input will not increase output.

Aliasing occurs when the detected Doppler frequency exceeds the Nyquist limit. It is characterized on the spectral display by the Doppler peaks going off the display, top or bottom, and then continuing on the other side of the baseline. On the Color display an immediate change in color from one Nyquist limit to the other is seen.

Comet tail is a form of reverberation artifact produced when two or more strong reflectors are close together and have a high propagation speed. In this case, sound does not travel directly to a reflector and back to the transducer; and a strong linear echo appears at the reflector and extends deeper than the reflector.

Enhancement is an increased relative amplitude of echoes caused by an intervening structure of low attenuation.

Focal enhancement, also known as **focal banding**, is the increased intensity in the focal region that appears as a brightening of the echoes on the display.

Mirror imaging artifact is most commonly seen around the diaphragm; this artifact results from sound reflecting off another reflector and back.

Mirroring is the appearance of artifacts on a spectral display when there is improper separation of forward and reverse signal processing channels. Consequently, strong signals from one channel mirror into the other.

Multi-path positioning and **refraction** artifacts describe the situation in which the paths to and from a reflector are different. The longer the sound takes traveling to or from a reflector, the greater the axial error in reflector positioning (increased range). Refraction and multi-path positioning errors are normally relatively small and contribute to general degradation of the image rather than to gross errors in object location.

Propagation speed errors occur when the assumed value for propagation speed by the ultrasound system is incorrect. If the actual speed is greater than that assumed, the calculated distance to a reflector is too small, and the reflector will be displayed too far from the transducer. Speed error can cause a structure to be displayed with incorrect size and shape.

Range ambiguity can occur when reflections are received after the next pulse is transmitted. In ultrasound imaging, it is assumed that for each pulse produced, all reflections are received before the next pulse is sent out. The ultrasound system calculates the distance to a reflector from the echo arrival time assuming that all echoes were generated by the last emitted pulse. The maximum depth to be imaged unambiguously by the system determines its maximum pulse repetition frequency.

Reverberation is the continuing reception of a particular signal because of reverberation rather than reflection from a particular acoustic interface. This phenomenon is analogous to the effect created by mirrors positioned on opposite walls when an object, a head for instance, is placed between the mirrors. The image of the head is reflected back and forth infinitely between the two mirrors, creating the optical illusion of multiple heads. Reverberations are easily identifiable, because they are equally spaced on the display screen.

Scattering is the diffuse, low-amplitude sound waves that occur when acoustic energy reflects off tissue interfaces smaller than a wavelength. In diagnostic ultrasound, Doppler signals come primarily from acoustic energy back-scattered from red blood cells.

Shadowing is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the screen. This cloud, or shadow, is useful as a diagnostic clue.

Side lobes (from single-element transducers) and **grating lobes** (from array transducers) cause objects that are not directly in front of the transducer to be displayed incorrectly in lateral position.

Speckle appears as tissue texture close to the transducer but does not correspond to scatterers in tissue. It is produced by ultrasound wave interference and results in general image degradation.

Spectral broadening is a display phenomenon that occurs when the number of energy-bearing Fourier frequency components increases at any given point in time. As a consequence, the spectral display is broadened. Spectral broadening can indicate the disturbed flow caused by a lesion, and therefore it is important diagnostically. However, broadening can also result from interaction between flow and sample volume size, in which case it is an artifact.

Speed of sound artifacts occur if the sound propagation path to a reflector is partially through bone, and the speed of sound is greater than in the average soft tissue. Echo position registration artifacts will be produced. Reflectors appear closer to the transducer than their actual distance because of this greater speed of sound, resulting in a shorter echo transit time than for paths not containing bone.

Transducer Covers

Sterile transducer covers are required for intraoperative and biopsy procedures, and protective covers are recommended for transrectal, intravaginal, and transesophageal procedures, but in China and Japan, the covers are mandatory. Philips recommends the use of qualified covers.

For procedures for using transducer covers, see the instructions provided with the covers.

WARNINGS

- Latex is commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications and during biopsies. Examine the packaging to confirm latex content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in "FDA Medical Alert on Latex" on page 36.
- In neurosurgical applications, sterilized transducers should be used with sterile gel and a sterile pyrogen-free transducer cover.
- If the sterile transducer cover becomes compromised during an intraoperative application involving a patient with Creutzfeldt-Jakob disease, follow the recommendations described in "Transmissible Spongiform Encephalopathy" on page 213.
- Transducer covers are disposable and must not be reused.
- If an installed transducer cover is cut or contaminated before use, the probe should be cleaned and disinfected, and a new sterile cover installed.

Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage.

Storage for Transport

If a carrying case is provided with your transducer, always use the carrying case to transport the transducer from one site to another. Follow these guidelines to properly store transducers for transport:

- Make sure that the transducer is clean and disinfected before placing it in the case to avoid contaminating the foam that lines the carrying case.
- Place the transducer in the case carefully to prevent kinking of the cable.
- Before closing the lid, make sure no part of the transducer is protruding from the case.
- Wrap the case in plastic material containing air pockets (bubble wrap), and pack the wrapped case in a cardboard carton.
- To avoid damaging the shaft or steering mechanism of TEE transducers, do not bend or coil the flexible shaft of the transducer in less than a 0.30-m (1-ft) diameter circle.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Always store transducers in the transducer holders on the side of your system or on a securely mounted wall rack when you are not using them.
- Ensure the transducer holders are clean before storing transducers (see "Disinfecting System Surfaces" on page 239).
- Avoid storing transducers in areas of temperature extremes or in direct sunlight.
- Store transducers separately from other instruments to avoid inadvertent transducer damage.
- When storing transducers, use the cable-management clips to secure the transducer cable.
- Before storing transducers, make sure they are thoroughly dry.
- For TEE transducers, be sure the distal tip is straight and protected before storing the transducer.
- Never store a TEE transducer in the carrying case, except to transport it.

9 *Transesophageal Transducers*

A transesophageal echocardiography (TEE) study is performed with a transducer mounted in a gastroscope, which is positioned in the esophagus or stomach. TEE transducers offer images that are unobstructed by lungs and ribs, making them important diagnostic tools for conditions that transthoracic echocardiography cannot adequately image.

The system supports the compact X7-2t TEE transducer. The imaging array in the X7-2t transducer can be rotated electronically using controls on the transducer or on the control panel.

Operators of TEE Transducers

Philips TEE transducers are designed for use under the guidance of physicians who are properly trained in esophagogastroscopic techniques, according to currently approved relevant medical practices. Philips recommends that physicians operating any Philips TEE transducer have the following qualifications:

- Proficiency in recognizing and interpreting transesophageal imaging patterns
- Thorough familiarity with the safe operation, care, and maintenance of the ultrasound system and TEE transducers
- Thorough familiarity with the latest TEE methods through literature and seminars

Patient Safety During TEE Studies

Philips recommends that you practice using the TEE transducer controls before performing any procedure mentioned here. You must also be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound imaging system used with the TEE transducer, as well as proficient at interpreting the images generated.

You can help ensure patient safety when using a TEE transducer by following these guidelines:

- Use informed judgement when selecting patients for TEE studies.
- Verbally prepare each patient for the procedure before the study. See "Preparing Patients for TEE Studies" in the Help.
- Scrutinize the entire transducer and test all of the controls before each use. See "Checking the TEE Transducer" on page 196.
- Insert, remove, and operate the transducer properly.
- Ensure that the transducer handle does not rest on or touch the patient.
- Use protective equipment, such as a bite guard and a market-approved sterile transducer cover during a TEE study. See "TEE Accessories and Supplies" on page 205.
- Do not allow water or other liquids to come in contact with the transducer connector or the interior of the system, or to drip onto the keyboard.
- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious. See "Tip Fold-Over" in the Help.

To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings and cautions.

WARNINGS

- Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.
- Do not allow the TEE transducer to remain at a maximum deflection for long periods of time.
- Lock medial/lateral movement of the TEE transducer during insertion.
- Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.
- To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.
- Bite guards are mandatory; protective transducer covers are recommended for TEE transducers, but in China and Japan, the covers are mandatory. See "Electrical Safety and TEE Transducers" on page 184.

CAUTION

To avoid damaging gastroscope cables, be sure that the distal tip of the transducer is in the neutral (straight) position when inserting a transducer into, or removing it from, the transducer cover.

The TEE transducers are classified as Type BF isolated patient-applied parts, as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. To ensure safe operation of this transducer, read the cautions and warnings in the "Safety" section, especially those that address electrosurgical units, pacemakers, and defibrillators.

The following table summarizes patient safety problems, describes how to prevent them, and lists the sections in this manual where details are provided.

WARNING

If you encounter an irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

Ensuring Patient Safety During TEE Studies

Problem	Effect on Patient	Prevention	See
Mechanical damage	Severe trauma, cuts, bleeding, perforations	Inspect the transducer, using both sight and touch, before the study.	"Checking the TEE Transducer" on page 196
Electrical damage	Esophageal burns	Check the transducer for frayed insulation, kinks, or other abnormalities. Follow procedures for checking electrical safety.	"Electrical Safety and TEE Transducers" on page 184
Biting, scraping transducer	Tooth damage, esophageal burns	Always use a bite guard.	"Bite Guards" on page 205
Insufficient cleaning protocol	Spread of illness or disease	Thoroughly clean and disinfect the transducer after each use. Cover the tip and shaft with a transducer cover. Cover the imaging system with a disposable drape if highly pathogenic organisms are known or suspected.	"Transducer Care" section
Improper insertion or withdrawal	Esophageal cuts, bleeding, ligament damage, perforations	Never use force when inserting, removing, or manipulating the transducer. During insertion, lock the medial/lateral controls. During withdrawal, place the medial/lateral controls in freewheeling mode.	"TEE Study Guidelines" on page 198

Problem	Effect on Patient	Prevention	See
Pressure necrosis	Death of esophageal lining tissue	Keep deflection controls in freewheeling mode and unplug the transducer from the system when not imaging. Minimize the pressure applied to deflection area and distal tip. Do not let the distal tip displace a tissue area for more than 5 consecutive minutes.	"TEE Study Guidelines" on page 198
Increased transducer temperature	Esophageal burns	Use the TEE preset that has been established to minimize the effects of temperature. For febrile patients, use the Auto-Cool feature.	"Entering Patient Temperature" on page 202
Improper patient position	Transient unilateral vocal cord paralysis	Never use the transducer during any procedure requiring extreme neck flexion, such as sitting craniotomies.	"TEE Study Guidelines" on page 198
Nonisolated ESUs	Electrical burns	Only use isolated-output electrosurgical units (ESUs). The ESU label or service guide or your biomedical department should identify whether or not the ESU is isolated. Unplug transducer from the system when you are not imaging.	"Electrical Safety and TEE Transducers" on page 184
Defibrillation issues	Electrical burns	Remove the transducer from the patient before defibrillation.	"Electrical Safety and TEE Transducers" on page 184

Patient-Contact Parts

Latex is commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications and during biopsies. Examine the packaging to confirm latex content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See "FDA Medical Alert on Latex" on page 36.

NOTE

The ultrasound system and transducers discussed here do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducers.

Preventing TEE Transducer Problems

Meticulous inspection and correct and careful operation of the TEE (transesophageal) transducer is imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips one-year warranty or service contract. Transducer repairs necessitated by misuse of the transducer are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer and insulation from teeth or sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, causing fluid to enter the control head assembly, transducer handle, and the rest of the transducer
- Consistently applying too much force to the control wheels of a TEE transducer, which can break the steering mechanism

Review the following table to familiarize yourself with specific problems, to learn how to avoid them, and to identify the sections in this manual where details are provided. Philips also strongly recommends that you clearly post stringent protocols for TEE transducer care, based on the information in this manual, to minimize the chance of damage.

WARNING

For any other irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

Preventing TEE Transducer Equipment Problems

Problem	Effect on Equipment	Prevention	See
Current leakage	Serious electrical hazards	Check the transducer for cuts, frayed insulation, kinks, or other abnormalities.	"Checking the TEE Transducer" on page 196
Biting transducer	Mechanical and electrical hazards	Cover the patient's teeth with a bite guard (mandatory). Cover the distal tip and flexible shaft with a transducer cover (recommended).	"Bite Guards" on page 205
Forcing deflection controls	Steering mechanism broken	Operate the deflection controls gently.	"TEE Deflection Controls" on page 190
Incorrect storage	Possible damage to highly sensitive elements, cuts in flexible shaft	Suspend the transducer from a wall-mounted rack and the distal tip with a tip protector when not in use.	"Transducer Storage" on page 174
Internal exposure to liquids	Severe transducer damage that affects the image quality, the steering mechanism, and electrical safety	Never sterilize the transducer by using bleach, steam, heat, or ethylene oxide (EtO). Never immerse the steering mechanism in any disinfectant or liquid.	"Transducer Care" section

Electrical Safety and TEE Transducers

The ultrasound system and its transducers comply with common medical device electrical safety standards.

For electrical safety information about TEE transducers, see "Leakage Current and TEE Transducers" on page 184 and "Reducing Risks of Using TEE Transducers" on page 184.

For safety information on electrosurgical units, pacemakers, defibrillators, and related topics, see "Electrical Safety" on page 21.

Leakage Current and TEE Transducers

For the TEE transducers discussed in this document, the insertion tube and tip are Type BF  , as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. Within the flexible shaft, all active circuits and conductors are surrounded by a chassis-grounded shield that runs the length of the transducer.

If the outer layer of the shaft is punctured or cracked, a patient's esophagus could be exposed to chassis leakage current. This leakage current is not hazardous provided that the ground connector (third wire) in the ultrasound system power cable is intact and connected to a properly grounded wall outlet. Even if the ground connector breaks, leakage current is in compliance with the limits noted in IEC 60601-1:1995.

Leakage hazards are further reduced when the ultrasound system is plugged into an isolated power outlet, which is standard in most operating rooms.

Reducing Risks of Using TEE Transducers

To reduce the possibility of electrical risks associated with use of TEE transducers, follow these recommendations:

- Visually and tactually inspect a TEE transducer for bumps, cracks, and cuts before each TEE exam. A small bump on the shaft surface could indicate that

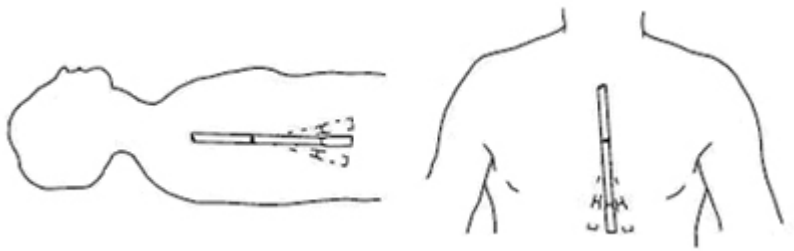
a strand from the ground shield has broken and is beginning to puncture the outer layer. If you suspect a problem with the flexible shaft, perform the electrical safety check procedure. See "TEE Leakage Current Test" on page 206.

- Use electrosurgical units (ESUs) that have isolated outputs. Return fault/ground fault detection circuits provide additional protection. To determine if an ESU has an isolated output, read the label on the ESU, see the ESU service guide, or ask a biomedical engineer.
- Require periodic electrical safety checks to ensure that the grounding system in your area remains intact.
- If the transducer is left in a patient during periods when imaging is not taking place, unplug the transducer from the system to reduce the possibility of leakage current or ESU interaction. Also make sure that the deflection control brakes are off and that the transducer is in freewheeling mode.

TEE Deflection Control Basics

The deflection controls on the TEE transducer move the deflection area, located between the distal tip and flexible shaft. The deflection area bends when you operate the controls, permitting anterior, posterior, and lateral positioning.

Deflection Control Movement



To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings. See "TEE Transducer References" on page 210.

WARNINGS

- Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.
- Lock medial/lateral movement of the TEE transducer during insertion.
- Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.
- Do not allow the TEE transducer to remain at a maximum deflection for long periods of time.
- To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.

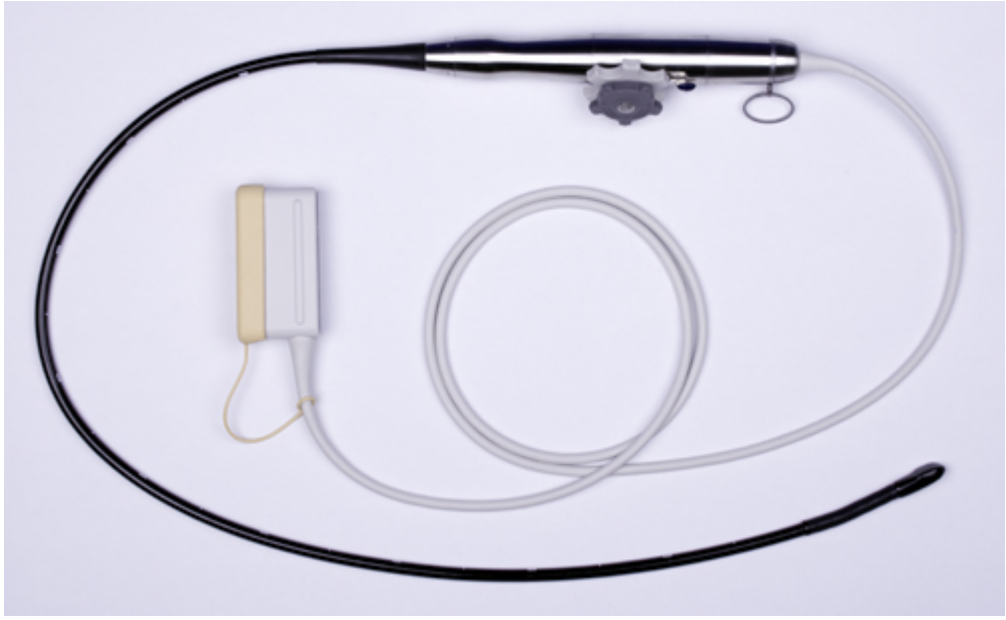
Connecting a TEE Transducer

To connect a TEE transducer, insert its connector fully into the receptacle and move the locking lever up.

X7-2t TEE Transducer Description

The X7-2t TEE transducer is described below.

X7-2t TEE Transducer



X7-2t TEE Transducer Features and Specifications

Features	Ultraband transducer technology sensor for Harmonic imaging. Enables high-resolution imaging and 360-degree views of the heart, unobstructed by lungs and ribs. Capable of Harmonic imaging, contrast research, Color imaging, steerable CW Doppler mode and PW Doppler mode, frequency agility, and electrocautery suppression. Tip surface constantly monitored for patient safety. Convenient hanging ring.
Specifications	**Tip:** 1.5 cm (0.6 in) wide, 3.5 cm (1.4 in) long **Shaft:** 1.0 cm (0.4 in) wide, 1.0 m (3.3 ft) long

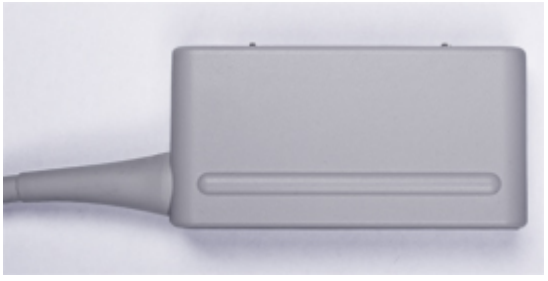
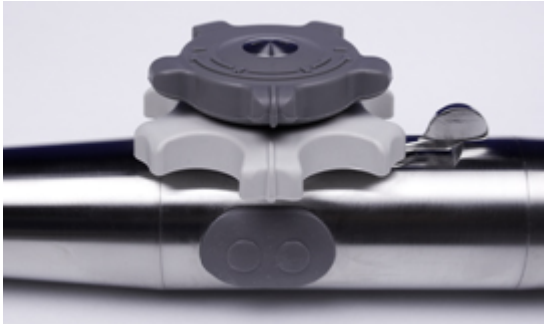
NOTE

Philips recommends that you use the TEE transducer only on patients weighing at least 30 kg (66 lb), to ensure the esophagus can comfortably accommodate the transducer.

TEE Transducer Components

Philips recommends familiarizing yourself with the controls and parts of the TEE transducer before using it in a study.

TEE Transducer Components

Component	Description
	Distal tip
	Transducer connector
	Transducer handle
	Deflection controls

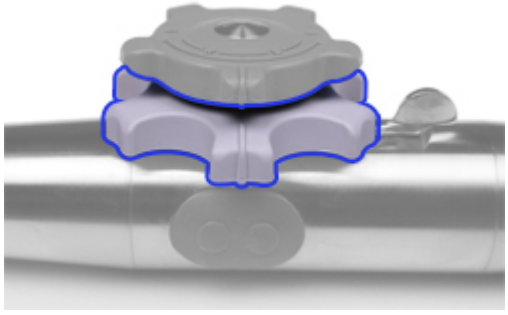
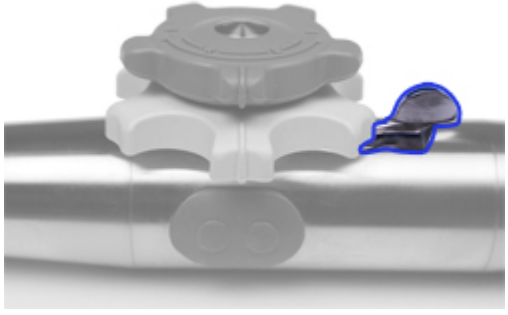
TEE Deflection Controls

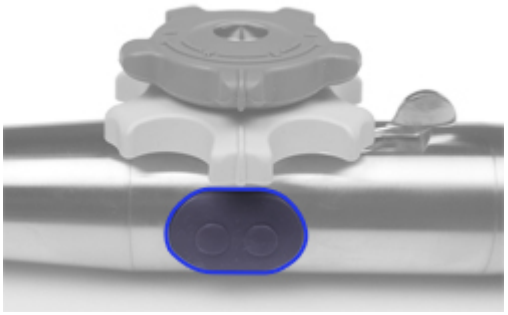
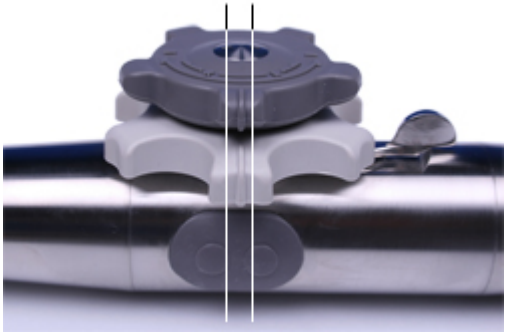
The deflection controls and brake for the X7-2t TEE transducers are shown below.

The smaller knob controls medial/lateral movement, while the larger knob controls anterior/posterior movement. To place the tip of the TEE transducer into the neutral position, align the ribs on each knob with the center of the array rotation buttons (as shown below).

The knobs can be controlled by a detent brake that holds the tip position without locking it in place. This allows the tip to straighten if it meets additional resistance. When the detent brake actuator is rotated to the right (as shown) both knobs are in the freewheeling mode. When the detent brake actuator is centered, the small knob (medial/lateral movement) is in the detent mode, and when the actuator is rotated to the left, both knobs are in the detent mode.

TEE Transducer Controls

Control	Description
	Medial/lateral control
	Anterior/posterior control
	Detent brake actuator

Control	Description
	Image plane rotation buttons
	Neutral position indicators, showing no deflection

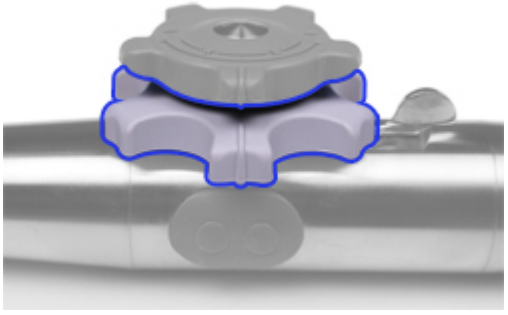
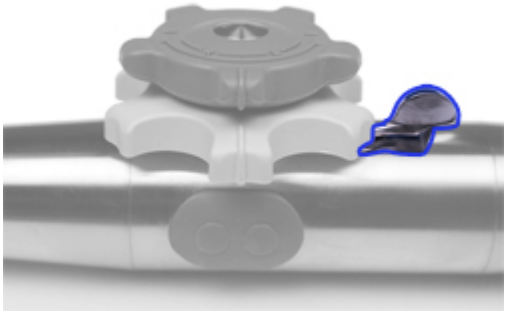
Manipulating the TEE Tip

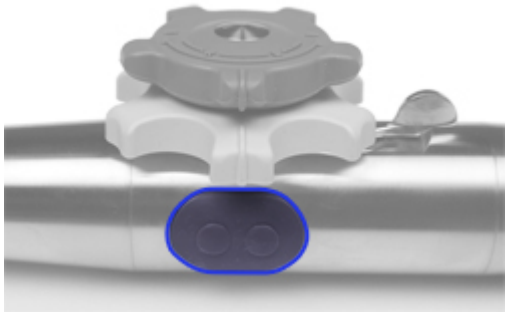
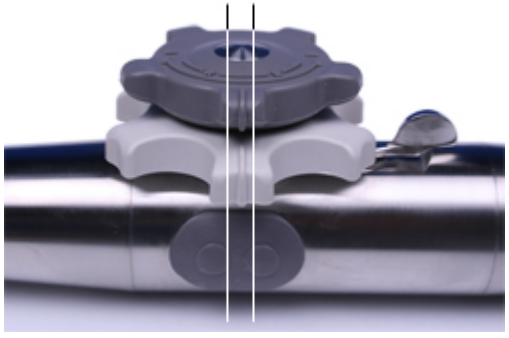
Review the warnings and caution in "Patient Safety During TEE Studies" on page 177 and "TEE Deflection Control Basics" on page 185 before using the transducer in a study.

1. Turn the detent brake actuator fully away from the image plane rotation buttons to put both knobs into freewheeling mode.
2. Turn the large knob to deflect the tip in the anterior/posterior plane.
3. Turn the small knob to deflect the tip in the medial/lateral plane.
4. When the tip is positioned properly, do one of the following:
   - Turn the detent brake actuator fully toward the image plane rotation buttons to put both knobs in detent mode.

- Center the detent brake actuator to put only the small knob (medial/lateral movement) in the detent mode.

TEE Transducer Controls

Control	Description
	Medial/lateral control
	Anterior/posterior control
	Detent brake actuator

Control	Description
	Image plane rotation buttons
	Neutral position indicators, showing no deflection

Rotating the TEE Image Plane

You can rotate the image plane on the TEE transducer to achieve a 360-degree view of the heart. You can use either the image plane rotation buttons on the transducer handle or the controls on the system. Rotation stops when you release either button.

The current degree of rotation appears in either the upper or lower part of the display, depending on image orientation. Because the center of the image array is the pivot point, you can achieve a 360-degree view.

- To rotate the TEE transducer image plane using the transducer controls, do either of the following :

- To rotate the imaging plane toward the 180-degree position, press the image plane rotation button that is distal to the system.
- To rotate the imaging plane toward the 0-degree position, press the button that is proximal to the system.

- To rotate the X7-2t transducer image plane using a system control, turn the **Seek Angle** quick key.

Checking the TEE Transducer

Before each TEE study, carefully inspect the transducer and try the controls.

1. Inspect the transducer:
   - Carefully inspect the entire surface of the distal tip and flexible shaft for protrusions, holes, dents, abrasions, cuts, burrs, or cracks, which could be extremely hazardous to both you and your patient.
   - Carefully feel the tip and shaft, and inspect the entire transducer. If you suspect an electrical problem, follow the electrical safety check procedure described in "TEE Leakage Current Test" on page 206.
   - Check for excessive flexibility in the tip, particularly in the medial/lateral direction. *Do not* use the transducer if the tip is extremely flexible. If you have any questions about tip flexibility, contact your Philips service representative.
2. Verify the operation of the controls:
   - Use the deflection controls to position the tip in every possible direction, both to ensure that the controls work properly and to get used to the feel of the TEE transducer. Make sure that the controls operate smoothly without binding, and that you can achieve all possible positions easily before introducing the TEE transducer into the patient.
   - Test the detent brakes and freewheeling mode. Remember that the controls must be in freewheeling mode (no deflection and no brake resistance) when repositioning or withdrawing the transducer, as well as whenever you are not imaging. See "Manipulating the TEE Tip" on page 192.

Special Considerations for TEE Studies

Special considerations regarding TEE studies are advisable for patients with existing gastroesophageal abnormalities, such as esophageal varices, hiatal hernia, tumor, diverticula, esophageal webs and rings, fistulae, or peptic ulcers, as well as for patients who have had anti-reflux procedures. In addition, you should do the following:

- Consider the patient's size and ability to accommodate the transducer tip and shaft.
- Check the patient's history for gastroesophageal disease or difficulty swallowing.
- Evaluate the potential overall effects of any treatment that the patient is undergoing, such as mediastinal radiation, chemotherapy, anticoagulation, or steroid therapy.
- Be aware that you may discover unsuspected esophageal pathology during a study. Be alert for congenital problems with the esophagus or stomach, particularly with pediatric patients.
- When examining a patient with an above-normal temperature, use the Auto-Cool feature and enter the patient temperature. The Auto-Cool feature is described in "Entering Patient Temperature" on page 202.

This list is not comprehensive. Rather, it suggests areas to investigate when considering TEE for a particular patient.

Preparing Patients for TEE Studies

These suggestions for pre-study patient preparation do not constitute an exhaustive list of all possible factors to explore before performing transesophageal echocardiography, nor do they imply medical protocols. Instead, they reflect basic guidelines resulting from extensive consultation with physicians throughout

the design, development, and clinical investigation periods of Philips TEE transducers.

- Besides gathering routine background information such as current medication and allergies, investigate any history of chronic obstructive lung disease, esophageal strictures, varices, or bleeding.
- Thoroughly explain the procedure to the patient before the study.
- Inform the patient not to eat or drink for at least 6 hours before the study.
- Advise the patient that he or she should not plan to drive after the study, because sedatives are often used.
- Follow institutional guidelines for obtaining patient consent for a transesophageal echocardiography (TEE) study.
- Be sure that a recent ECG, CBC, and SMA6 are available as a baselines.

TEE Study Guidelines

During a TEE study, an assistant can provide oral and pharyngeal suctioning of the patient and can monitor the patient's blood pressure and general responses. For unexpected occurrences, an emergency cart with basic life-support equipment should be ready. Throughout the study, it is important to carefully monitor the patient's reactions and to ensure that ventilation and vital signs are stable.

In the operating room, do not use TEE transducers during surgical procedures requiring extreme neck flexion, such as sitting craniotomies. The following are important guidelines for TEE studies. (See "TEE Transducer References" on page 210.)

- Maintain a patent airway. For surgical patients, endotracheal intubation establishes a stable, patent airway before insertion of the transducer. For patients who are awake, carefully monitor the patient's breathing at all times.
- Minimize the possibility of pressure necrosis (tissue death). Do not let the distal tip displace any one segment of tissue for more than 5 consecutive minutes. Also make sure the deflection area and the distal tip are in the position of least potential pressure. Be sure that the transducer is in a freewheeling mode and unplugged whenever you are not imaging.

- Prevent potential esophageal damage. Philips recommends that you stop TEE scanning and unplug the transducer from the system during periods of poor perfusion, circulatory arrest, or the hypothermic phase of open heart surgery. To discontinue scanning, unlock the transducer connector.
- Before each TEE study, carefully inspect the transducer, as described in "Checking the TEE Transducer" on page 196. A thorough inspection procedure is required for the safety of the patient and yourself, and to ensure the continued correct functioning of the transducer.
- Refrain from handling the distal tip whenever possible. If you must handle the distal tip, grasp it on the sides. Do not touch the top or bottom. Support the transducer's proximal head, either by having an assistant hold the steering mechanism or by clamping the transducer at the steering mechanism. Ensure that the clamp does not interfere with steering, and do not clamp any part of the flexible shaft, as this will damage the transducer.

Tip Fold-Over

On rare occasions, the tip of a TEE transducer has folded over during insertion. The effects can be serious if the situation is handled incorrectly. The esophagus can be scraped, perforated, or otherwise damaged.

For more information on tip fold-over, see "Tip Fold-Over" in the Help.

TEE Temperature Sensing

The transesophageal transducers contain built-in temperature sensors near the distal tip. The sensor monitors the transducer's temperature to prevent potential burning of esophageal tissue. The patient's actual temperature is required to accurately estimate the distal tip temperature. By default the system assumes that the patient temperature is 37°C (98.6°F). You must manually enter the actual patient temperature if it is above 37°C (98.6°F).

The system default setting is for a normal patient core temperature of 37°C (98.6°F). The system calculates the distal tip temperature through an algorithm that relates an internal temperature measurement to the temperature of the distal tip. To respond to an elevated patient temperature, turn the **Patient**

Temp control. For more information, see "Entering Patient Temperature" on page 202.

The Auto-Cool feature provides warning messages at two points:

- At 41.0°C (105.8°F), the **TEE auto cool imminent** message appears.
- At 42.5°C (108.5°F), the **TEE auto cool in progress** message appears, and the system automatically stops scanning.

WARNING

If the patient temperature is above 37°C (98.6°F) and the **Patient Temp** control is set below the actual patient temperature, then the system can overestimate the temperature of the TEE transducer's distal tip. This can prematurely trigger the Auto-Cool feature. If the patient temperature is at or near 37°C (98.6°F) and the **Patient Temp** control is set above the actual patient temperature, then the system can underestimate the temperature of the distal tip. This can expose patients to excessive temperatures.

Ensuring Safe TEE Temperatures

To ensure patient safety and to avoid unnecessary interruption while scanning, follow these suggestions:

- Ensure distal-tip-temperature accuracy by entering an accurate patient core temperature.
- Decrease the transducer temperature by decreasing acoustic output power by 2 dB before introducing a TEE transducer. This change should produce only a very minor degradation of image quality. It may be necessary under certain scanning conditions to return the acoustic power to its default setting to achieve optimum image quality. For information about controlling the power, see the Help.
- Use the TEE Manual Auto-Cool Safety feature to enter the patient temperature if it is above 37°C (98.6°F) as described in "Entering Patient Temperature" on page 202.

Manual Auto-Cool Feature

Use the TEE Manual Auto-Cool safety feature to enter above-normal patient temperatures. When the temperature display is enabled, you can see both the patient temperature and the distal tip temperature while scanning.

NOTE

The patient temperature displayed on the ultrasound screen is always either 37°C (98.6°F) or the temperature that you manually enter. The system does not monitor or report the actual patient temperature.

If the distal tip temperature reaches 41°C (105.8°F), a warning message appears and the transducer temperature is displayed in inverse video. If the temperature reaches 42.5°C (108.5°F), a warning appears with the patient and the transducer temperatures, and the system stops imaging until the distal tip cools to below 42°C (107.6°F). If the distal tip temperature reaches 43.5°C (110.3°F), the system shuts down. You may need to restart the system by turning it on.

WARNINGS

- To avoid the risk of esophageal burn for adult patients, minimize the time spent imaging at distal tip temperatures in excess of 42°C (107.6°F). Exposure should be limited to 10 minutes or less at 42°C (107.6°F) or higher.
- Sufficient data on thermal tolerance of the esophagus in neonate and pediatric patients does not exist, but it is likely these patients are more vulnerable than adults. Minimize the time spent imaging at distal tip temperatures in excess of 41°C (105.8°F).

Patient Temperature

Entering a patient's temperature enables the Auto-Cool feature to calculate tip temperature more accurately, which can prevent unnecessary interruptions while scanning. If a patient's temperature is above normal, entering a temperature can avoid exposing the patient to excessive temperatures.

Always check the patient's temperature before inserting a TEE transducer. If it is above normal, whether from fever or therapeutic heating from a cardiac bypass heart-lung machine, perform the procedure in "Entering Patient Temperature" on page 202 before inserting the transducer. Also, follow that procedure if a patient's temperature rises during a study.

Measure the patient's core temperature, or more specifically, the actual temperature in the esophagus. For patients undergoing surgery, determine the temperature in the esophagus by direct measurement or by monitoring the temperature of blood returning from the bypass pump heat exchanger.

For closed-chest situations, rectal temperature is the best estimate of core temperature. You can also use oral temperatures, even though they can be one degree lower than the core temperature. If you measure an auxiliary temperature, which can be two degrees lower than the core temperature, add one or two degrees.

Entering Patient Temperature

1. If necessary, select the TEE transducer.
2. Measure the patient's temperature using the techniques described in "Patient Temperature" on page 201.
3. Turn the **Patient Temp** quick key to enter the patient's measured temperature.

NOTE

Each time you turn off or reset the system, or enter a new patient ID, the system assumes that the patient temperature is 37°C (98.6°F).

Temperature Display

Both the patient temperature (assumed or entered) and the transducer temperature appear on the display when enabled. On the display, the patient temperature is labeled **Pat. T**, and the transducer temperature is labeled **TEE T**.

TEE Temperature Display

A less-than sign (<) after **TEE T** indicates that the transducer's distal tip temperature is below the patient temperature (**Pat. T**) assumed by the system, which is either 37°C (98.6°F) or the temperature you entered.

Customizing the Temperature Display

1. Press the **Setup** key.
2. On the **System** tab, select **Celsius** or **Fahrenheit** for **TEE Temperature Units**.
3. Click **Apply** to apply your changes to this session only, or click **Save** to save your changes to a preset.

Resuming Imaging After Auto-Cool

If the distal tip temperature drops below 42.0°C (107.6°F), the system resumes imaging. If the Auto-Cool message persists longer than 1 minute or an error message appears, contact your Philips service representative.

If the distal tip temperature reaches 43.5°C (110.3°F), the system shuts down. You may need to restart it by pressing the **On/Off** button.

WARNING

The **Reconnect the Transducer** error message is often caused by a poorly seated transducer connector, but it could be caused by a failure in the Auto-Cool safety logic. In the case of a logic failure, distal tip temperatures could reach 46.5°C (115.7°F) in hyperthermic patients (40°C to 41°C or 104°F to 106°F) before the error causes scanning to stop. At this temperature, esophageal burns may occur (see the "TEE Transducer References" section in the *User Manual*).

1. Move the locking lever to the unlocked position  , and pull the connector out of the receptacle.
2. Reseat the connector in the receptacle and turn the locking lever clockwise.
3. Select the transducer and preset.
4. If the system does not resume imaging after the transducer has initialized, shut down the system and then restart it.

Patient Care After a TEE Study

Follow your institutional guidelines for post-TEE studies. Additionally, you might want to include the following recommendations in your guidelines as part of your post-TEE study routine.

- Inspect the patient's throat for any bleeding.
- Examine the patient for postural hypotension or difficulty walking.
- Instruct the patient to contact you immediately if he or she experiences any fever, chills, chest pain, or bleeding.
- Instruct the patient not to eat or drink for at least 2 hours or until swallowing returns to normal after anesthesia has worn off. It is especially important that the patient not ingest hot foods or fluids during this period.
- Follow up with a call to the patient the day after the a study to make sure there are no complications.

TEE Accessories and Supplies

Each TEE transducer comes with disposable bite guards and a disposable tip protector. Bite guards, TEE transducer covers, tip protectors, and disposable drapes are described here. For information on ordering TEE accessories, see "Supplies and Accessories" on page 18.

Bite Guards

WARNING

The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions. For more information, see "FDA Medical Alert on Latex" on page 36.

CAUTION

Damage caused when patients bite or scrape a TEE transducer is not covered in the transducer warranty or your service contract. Use bite guards to help prevent such accidents.

All patients must wear a bite guard during a TEE study. A bite guard prevents dangerous transducer mechanical and electrical malfunctions caused by involuntary biting. Even anesthetized patients require bite guards to prevent damage to their teeth and to the transducer. Philips supplies disposable bite guards that are suitable for both awake and anesthetized patients.

TEE Transducer Covers

WARNING

Transducer covers often contain natural rubber latex, which may cause allergic reactions. For more information, see "FDA Medical Alert on Latex" on page 36.

Philips recommends the use of a market-approved transducer cover during every TEE study.

For procedures on using transducer covers (protective sheaths), see the instructions provided with the covers.

Tip Protectors

When not using a carrying case to transport a TEE transducer, use a tip protector on its distal tip. The tip protector helps prevent serious damage to the transducer lens. Philips supplies tip protectors designed for each of its TEE transducers.

Disposable Drapes

During studies in which you believe contamination of the imaging system can occur, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

TEE Leakage Current Test

Regularly perform the electrical safety check described here to determine if there is a hole in a transducer's outer insulating layer. This procedure detects liquid pathways to the interior parts of the transducer shaft and tip by measuring third-wire leakage current. You can perform this procedure with any commercially available safety analyzer that is designed for hospital use.

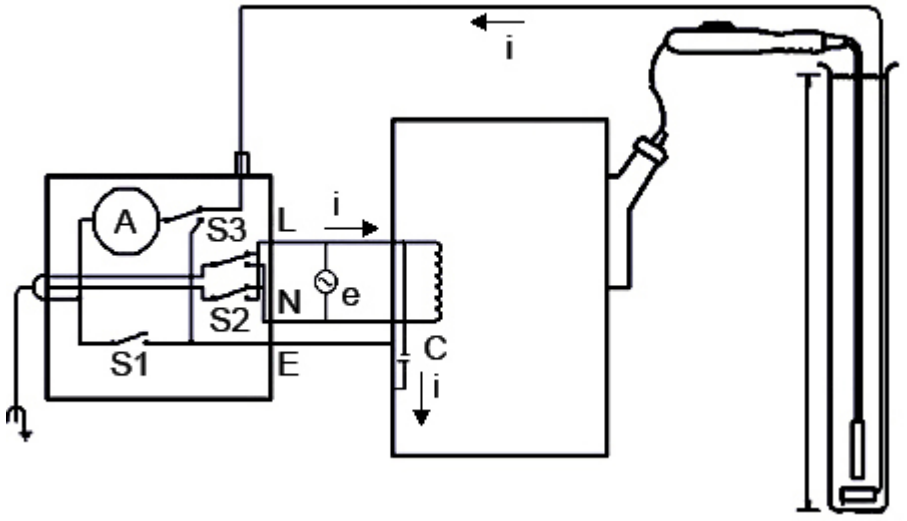
WARNING

Only a technically qualified person should perform the leakage-test procedure.

TEE Test Background

The test procedure (see figure) involves making an AC measurement of the ultrasound system current without a transducer. The results are then compared with the current measured when it is forced to flow through the insulating layer of the TEE transducer. If the two currents are nearly the same, it means there is a hole in the transducer's outer insulating layer that must be fixed before using the transducer.

Electrical Safety Check for TEE Transducers



TEE Leakage Current Test

Symbol	Definition
C	Stray capacitance from the ultrasound system power wiring to the system grounded metal chassis (1 to 3 MΩ reactance)
Z	Impedance between the metal parts of the TEE transducer and a test electrode placed in the bucket of saline solution (about 850 kΩ with an intact outer insulating layer, 500 Ω with a hole in the layer)
A	Microammeter to measure third-wire current, either directly from the chassis or through Z to the test electrode
e	Line power source, either 110 Vac or 220 Vac
I	Current caused by e and stray capacitance, and optionally Z
S1	Open earth lift ground switch
S2	Line polarity switch
S3	Microammeter switch
L	Line mains supply
N	Neutral mains supply
E	Earth ground

Current I, driven by line supply e, flows through all stray capacitances between the primary wiring and the ultrasound system's metal chassis. Ordinarily, current then flows from the metal chassis through S3 and back to e through a third-wire ground. When S3 is thrown in the other position, current I is forced:

- From the chassis through the metal parts of the transducer
- Through impedance Z, produced by the insulating layer that covers the metal parts of the transducer and the saline solution
- Through the test electrode

Saline generally presents an impedance of about 500 Ω, so Z will vary between 850 kΩ and 500 Ω, depending on whether or not there is a conductive pathway caused by a hole in the transducer's insulating layer.

CAUTION

Do not make a DC measurement of impedance. This could set up a voltaic cell, with the metal of the transducer and a test electrode in the salt bath forming the two electrodes and an electrolyte. Such a voltaic cell produces inaccurate resistance measurements.

You need the following equipment to perform the electrical safety check procedure:

- Dempsey 432HD or 232D safety analyzer or equivalent
- Philips 2110A Disinfection Basin or equivalent
- Saline solution, 9 grams (0.3 oz) of salt to 1 liter (1 qt) of tap water, or one of the tested disinfectants listed in the "Transducer Care" section

Testing TEE Transducer Leakage Current

For a list of the equipment needed to perform the electrical safety test procedure, see "TEE Test Background" on page 206.

WARNING

Only a technically qualified person should perform this procedure.

1. Gather the equipment in the preceding list.
2. Fill the basin to the fill line with saline solution.
3. Place the distal tip and shaft of the transducer into the basin.
4. Connect the transducer to the system.
5. Plug the ultrasound system's power cord into the test receptacle on the safety analyzer.
6. Attach a lead from the safety analyzer binding post labeled RL to a metal plate submerged in the basin.
7. On the safety analyzer, set the **Leads** switch to **RL**. Set the **Line Polarity** switch (S2) to **NORMAL**.

8. Turn on the safety analyzer and the ultrasound system.
9. Set the **Mode** switch (S3) on the safety analyzer to the **Case Leakage - Ground Conductor** position. Press the **Lift Ground** switch (S1) on the safety analyzer and record the chassis leakage current.
10. Set the **Mode** switch (S3) on the safety analyzer to the **ECG** position. Press the **Lift Ground** switch (S1) on the safety analyzer and record the patient leakage current.

The transducer fails the test if the patient leakage current recorded in step 10 is greater than 80% of the chassis leakage current recorded in step 9.

This failure indicates that there is a hole in the insulating layer of the TEE shaft. A hole enables a conductive pathway to internal metal parts of the transducer and presents a potentially hazardous condition to a patient undergoing external defibrillation or electrosurgery. A hole also allows invasion of organic material, making it difficult to completely disinfect all portions of the transducer. For these reasons, the transducer must be repaired before it is used.

TEE Transducer References

Cucchiara, R.F., et al. "Air Embolism in Upright Neurosurgical Patients: Detection and Localization by Two-dimensional Transesophageal Echocardiography." *Anesthesiology*, 353-355, 1984.

Gussenhoven, Elma, et al. "Transesophageal Two-dimensional Echocardiography: Its Role in Solving Clinical Problems." *Journal of the American College of Cardiology*, 975-979, 1986.

Radwin, Martin, et al. "Transesophageal Echocardiography: Intubation Techniques." *Philips Application Note 5091-2804E*, 1992.

Urbanowitz, John H., et al. "Transesophageal Echocardiography and Its Potential for Esophageal Damage." *Anesthesiology*, Vol. 72, No. 1, 1990.

10 Transducer Care

This section contains information on cleaning, disinfecting, and sterilizing transducers compatible with your system, as well as cleaning and disinfecting system surfaces. This section also lists the ultrasound gels that are safe to use with the transducers compatible with your system.

These instructions are intended to assist in effective cleaning, disinfection, and sterilization. In addition, these instructions will help avoid damage, which could void your warranty, during cleaning, disinfection, sterilization, and gel use.

Disinfectants and Gels Safety

Observe the following warnings and cautions when using disinfectants and gels. More specific warnings and cautions are included within the various procedures in this section and on the labels of the cleaning or disinfection solutions.

WARNINGS

- Disinfectants listed in "Disinfectants Compatibility" on page 229 are recommended because of their chemical compatibility with product materials, not their biological effectiveness. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 214. Also, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- Some transducers cannot be sterilized. For intraoperative procedures, high-level disinfection and the use of a sterile transducer cover and gel (as described in the instructions provided with the transducer cover) is an accepted method of infection control. See the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," September 30, 1997. The guidance document is located on the following Web site: www.fda.gov/cdrh/ode/ulstran.pdf
- Sterile transducer covers with sterile ultrasound transmission gel are required for intraoperative and biopsy procedures, and protective covers are recommended for transrectal, intravaginal, and transesophageal procedures, but in China and Japan, the covers are mandatory. Philips recommends the use of qualified covers.
- Bite guards are mandatory for TEE transducers. See "Electrical Safety and TEE Transducers" on page 184.
- Do not apply the transducer cover and gel until you are ready to perform the procedure. Transducers should not be left soaking in gel.
- In neurosurgical applications, sterilized transducers should be used with sterile gel and a sterile pyrogen-free transducer cover.

- Transducer covers can contain natural rubber latex, which may cause allergic reactions in some individuals. See "Latex Product Alert" on page 213.

For information on ordering transducer covers, contact CIVCO Medical Solutions (see "Supplies and Accessories" on page 18).

Latex Product Alert

Philips ultrasound systems and transducers do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any ultrasound transducer, including transthoracic, intraoperative, and transesophageal echocardiography (TEE) transducers. It also is not used on Philips ECG cables for the products in this manual.

WARNING

The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions.

For information on allergic reactions to latex-containing medical devices, see "FDA Medical Alert on Latex" on page 36.

Transmissible Spongiform Encephalopathy

WARNING

If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Heath Organization: WHO/CDS/APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

Acoustic Coupling Medium

For proper transmission of the acoustic beam, use the ultrasound transmission gel supplied by or recommended by Philips, or another glycol-, glycerol-, or water-based acoustic coupling medium.

CAUTION

Do not use mineral oil, oil-based couplants, gels with lotions or emollients of any kind, or other unapproved materials, because they might damage the transducer.

Choosing a Disinfectant

To choose an appropriate disinfectant, you first must determine the required level of disinfection, based on the device classification.

Levels of Disinfection by Device Classification

Classification	Definition	Level of Disinfection
Critical	Device enters otherwise sterile tissue (for example, intraoperative applications)	Sterilization [1]
Semi-critical	Device contacts mucous membranes (for example, intracavity applications)	High
Noncritical	Device contacts intact skin	Intermediate or low

1. High-level disinfection and the use of a sterile gel and a sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for ultrasound transducers. See the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," September 30, 1997. For more information, see the following Web site: www.fda.gov/cdrh/ode/ulstran.pdf

General Cleaning for All Transducers

These general cleaning instructions are indicated for all transducers. It is important that you clean the transducer and cable according to the following procedures.

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTIONS

- Transducers *must* be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. Be sure to follow the manufacturer's instructions when using disinfectants.
- Do not allow sharp objects, such as scalpels or cauterizing knives, to touch transducers or cables.
- When handling a transducer, do not bump the transducer on hard surfaces.
- Do *not* use a surgeon's brush when cleaning transducers. The use of even soft brushes can damage transducers.
- During cleaning, disinfection, and sterilization, orient the parts of the transducer that must remain dry higher than the wet parts until all parts are dry. This will help keep liquid from entering unsealed areas of the transducer.
- Be sure to use the proper concentration of enzymatic cleaner and rinse thoroughly.

Cleaning a Transducer

1. After every patient study, wipe the ultrasound transmission gel off of the transducer.
2. Disconnect the transducer from the system and remove any accessories attached to or covering the transducer.
3. Use a soft cloth lightly dampened in a mild soap or an enzymatic cleaner (in accordance with the manufacturer's instructions) to remove any particulate matter or body fluids that remain on the transducer or cable. Enzymatic

cleaners should have a pH of 6.0 to 8.0. Those cleaners are further diluted during use. For a list of approved enzymatic cleaners, see "Disinfectants Compatibility Table" on page 231.

4. To remove remaining particulate and cleaning residue, rinse thoroughly with water up to the immersion point shown in "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 220.
5. Wipe with a dry cloth.

Disinfecting Transducers using a Wipe or Spray Method

To disinfect transducers, you can use either an immersion method or a wipe method with a disinfectant recommended by Philips Ultrasound. Use the method that is biologically appropriate, as described in "Choosing a Disinfectant" on page 214.

This topic provides instructions on using the wipe or spray method.

NOTE

Transducers can be disinfected using the wipe method only if the product labeling of the compatible disinfectant you are using indicates it can be used with a wipe method.

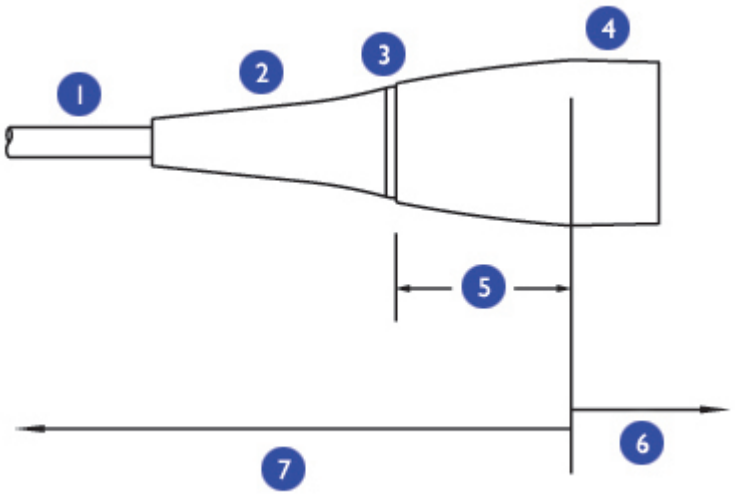
WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTION

The use of 70% isopropyl alcohol (rubbing alcohol) on transducers is restricted. Wipe only the distal tip of the transducer up to 2.5 cm (1 in) from the strain relief/housing joint with an isopropyl alcohol solution. Do not use isopropyl alcohol on the strain relief/housing joint, the strain relief, or the cable, or on TEE transducers (except the handle). Isopropyl alcohol can cause damage to these parts of the transducer. This damage is not covered by the warranty or your service contract.

Restricted Use of Isopropyl Alcohol to Clean Transducers

	Description	Connector
1.	Cable	
2.	Strain relief	
3.	Strain relief/housing joint	
4.	Housing	
5.	2.5 cm (1 inch)	
6.	You can use alcohol in this area	
7.	Do not use alcohol in this area	

1. After cleaning the transducer and cable (see "General Cleaning for All Transducers" on page 215), wipe or spray the transducer and cable with a low-level disinfectant. Allow for the manufacturer's recommended contact time. For a list of compatible disinfectants, see "Disinfectants Compatibility" on page 229.
2. Remove any residue with a water-moistened soft cloth. Do not allow any solutions to air dry on the transducer.
3. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your Philips Ultrasound representative.

Cleaning and Disinfecting Cables and Connectors

The cables and connectors of all transducers can be disinfected using a recommended wipe or spray disinfectant. To protect the electronics in the connector, Philips advises use of the connector cover provided with imaging transducers when you disinfect near the connector. Kits are available from CIVCO Medical Solutions (see "Supplies and Accessories" on page 18).

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTIONS

- Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and voids the warranty.
- Orient the parts that must remain dry higher than the wet parts until all parts are dry.

1. Disconnect the device from the system.
2. Push the connector cover (provided with the transducer) onto the connector to protect against fluid splashing onto the contacts.
3. Orient the device and the connector so they are both facing up.

CAUTIONS

- Do not allow any type of fluid to enter the connector. Fluid in the connector may void the transducer or device warranty.
- Do not use a brush on the connector label.

4. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean the cable and the connector. A soft-bristled brush can be used to clean only the metal surfaces of the connector. Do not allow any type of fluid to enter the device. Be careful that fluid does not enter through the strain relief,

through the connector, through the electrical contacts, or through the areas surrounding the locking lever shaft and the strain relief.

WARNING

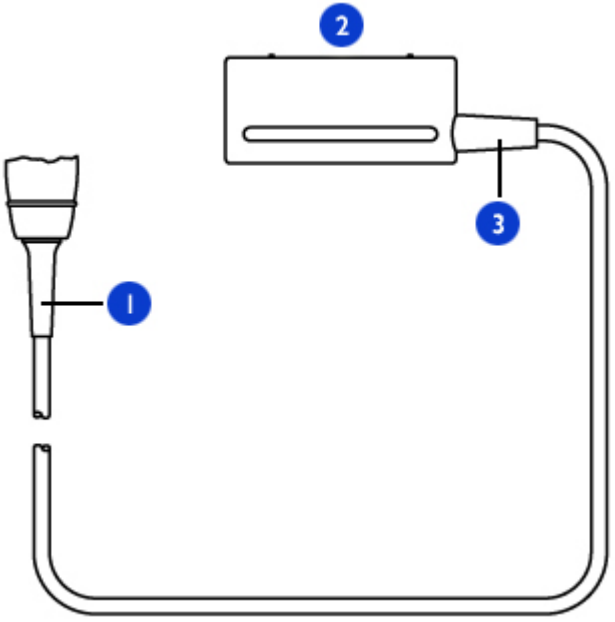
If a premixed solution is used, be sure to observe the solution expiration date.

CAUTIONS

- You can use an alcohol solution for disinfection on the connector only. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.
- Do not use any alcohol or alcohol-based products on the cable.
- Avoid disinfectant contact with the connector label.

5. Mix the disinfection solution compatible with your cable (see "Disinfectants Compatibility Table" on page 231) according to label instructions for solution strength.
6. Wipe or spray the cable and connector with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and duration of disinfectant contact with the cable. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Ensure that the disinfectant solution does not enter the device or the connector or come into contact with the connector label.
7. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
8. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your Philips Ultrasound representative.

Disinfecting Cables and Connectors

	Description	Cable and Connector
For cable disinfection, orient the device and the connector facing up (strain reliefs on the bottom). Wipe the strain reliefs, cable, and connector with a compatible disinfectant.		**Add drawing with CX50 connector** 
1.	Transducer strain relief	
2.	Electrical contacts	
3.	Connector strain relief	

Disinfection of Transducers by Immersion (High-Level Disinfection)

This topic provides information about using the immersion method to disinfect most transducers. Transesophageal (TEE) transducers require unique methods for disinfection by immersion. For details, see "Disinfecting TEE Transducers by Immersion" on page 223.

WARNING

If a premixed disinfectant is used, be sure to observe the expiration date.

CAUTIONS

- Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and voids the transducer warranty.
- Do not immerse transducers longer than the minimum time needed for your level of disinfection. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 214.

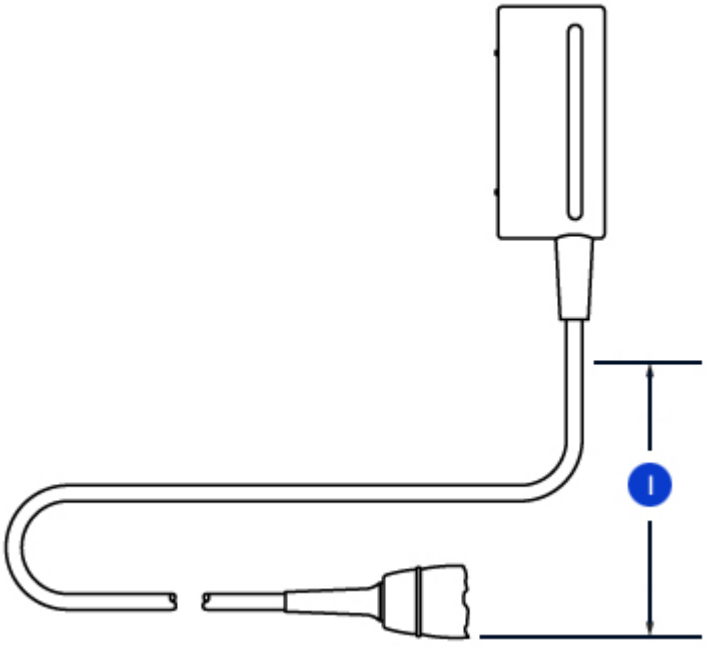
Disinfecting Transducers by Immersion

Before performing this procedure, read "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 220.

1. Clean the transducer according to "General Cleaning for All Transducers" on page 215.
2. Mix the disinfection solution compatible with your transducer (see "Disinfectants Compatibility Table" on page 231) according to label instructions for solution strength. A disinfectant listed in the table with the footnote “FDA 510(k) cleared” is recommended in the U.S.
3. Immerse the transducer into the appropriate disinfectant for your transducer as shown. Follow the instructions on the disinfectant label for the duration of transducer immersion. Do not immerse transducers longer than the minimum time needed for your level of disinfection.

Immersing Transducers

1. Immerse this section only, up to 5.1 cm (2 in) from the connector's strain relief



4. Using the instructions on the disinfectant label, rinse the transducer up to the point of immersion, and then air dry or towel dry with a sterile cloth.
5. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your Philips Ultrasound representative.

Disinfecting TEE Transducers by Immersion

WARNINGS

- If you use Cidex OPA Solution or other OPA-based disinfectants, residual solution may remain on your transducers if you do not carefully follow the manufacturer's instructions. Residual OPA on TEE transducers may cause temporary staining of the mouth and lip area and irritation or chemical burns of the mouth, throat, esophagus, and stomach.
- To minimize the effects from residual OPA, or any other disinfectant, Philips recommends the following:
  - Follow the disinfectant manufacturer's instructions very carefully. For example, the manufacturer of Cidex OPA recommends soaking transducers three times in fresh water.
  - Use a protective transducer cover during endocavity and TEE studies.
  - Use a sterile protective transducer cover with sterile ultrasound transmission gel during intraoperative and biopsy studies.
  - Limit the time that transducers are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer (for example, the manufacturer of Cidex OPA recommends a minimum of 12 minutes).

Disinfection by immersion is the accepted method of infection control for transesophageal transducers. Philips recommends that a protective transducer cover be used during studies.

Upon receiving your new transducer, disinfect it before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from a variety of pathogens. Establish and clearly post a cleaning procedure that includes the following steps.

Before performing this procedure, read "Disinfection of Transducers by Immersion (High-Level Disinfection)" on page 220.

1. Disconnect the transducer from the system.

2. Use the following procedure to remove all organic matter and other residue:
   a. Soak gauze pads in mild, soapy water. Do not use iodine-based soaps.
   b. Do one of the following:
   c. Wipe the distal tip and flexible shaft up to the control housing (steering mechanism) with the gauze pads. Use an enzymatic cleaner to assist in removing protein residuals. Enzymatic cleaners should have a pH of 6.0 to 8.0. Those cleaners are further diluted during use. Follow the manufacturer's instructions for dilution.

CAUTION

Do not rinse or immerse the control housing, cable, or connector.

3. Use water to rinse the distal tip and flexible shaft thoroughly.

CAUTIONS

- Do not bend the shaft into a circle with a diameter of less than 0.30 m (1 ft).
- Do not use bleach on the transducer and shaft.
- Do not use isopropyl alcohol-based products on the transducer and shaft.
- Do not soak the transducer for extended periods of time. Limit the time that transducers are soaked in disinfectant solution to the minimum time recommended by the disinfectant manufacturer.
- Do not rinse or immerse the connector or the portion of the cable near the connector.
- Do not immerse or rinse the steering mechanism.
- Follow the recommendations of the disinfectant manufacturer.

4. Disinfect the distal tip and flexible shaft by placing them in the appropriate disinfectant.
5. Remove the tip and shaft from the disinfectant and thoroughly rinse with water according to the instructions from the disinfectant manufacturer.
6. Check the transducer for any residual organic material. If any is present, remove it and disinfect the transducer again.

7. Dry the distal tip and flexible shaft with a sterile cloth or pad, or allow it to air dry.

CAUTION

The transducer steering mechanism is not sealed. If disinfectant or other fluid enters the steering mechanism, it will corrode the gears and electrical connections. Avoidable transducer damage is not covered by the warranty or service contract.

8. Lightly wipe only the steering mechanism and handle with a pad moistened with rubbing alcohol (70% isopropyl alcohol), or use T-Spray II as directed on the handle and steering mechanism.
9. Hang the transducer on a wall-mounted rack and let it air dry.

CAUTION

Never sterilize the transducer with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

Disinfecting TEE Transducers in an Automated Disinfector

The TD-100 is an automated disinfector available from PCI Medical. For more information about this product, see www.pcimedical.com. Use this disinfector only for those transducers listed as compatible in the results of a compatible-solution search on the Transducer Care Web site: (www.medical.philips.com/main/products/ultrasound/transducers/transcare/tranlanguage.html).

1. Disconnect the transducer from the system.
2. Use the following procedure to remove all organic matter and other residue:
   a. Soak gauze pads in mild, soapy water. Do not use iodine-based soaps.
   b. Do either of the following:

- Wipe the distal tip and flexible shaft up to the control housing (steering mechanism) with the gauze pads.
- Use an enzymatic cleaner to assist in removing protein residuals. Enzymatic cleaners should have a pH of 6.0 to 8.0. These cleaners are further diluted during use. Follow the manufacturer's instructions for dilution.

CAUTION

Do not rinse or immerse the control housing, cable, or connector.

3. Use water to rinse the distal tip and flexible shaft thoroughly.
4. Disinfect the distal tip and flexible shaft in the TD-100 Automated TEE Disinfector. Follow the manufacturer's instructions for operation of the disinfector.
5. Check the transducer for any residual organic material. If any is present, remove it and disinfect the transducer again.
6. Dry the distal tip and flexible shaft with a sterile cloth or pad, or allow it to air dry.
7. Lightly wipe only the steering mechanism and handle with a pad moistened with rubbing alcohol (70% isopropyl alcohol), or use T-Spray II as directed on the handle and steering mechanism.
8. Hang the transducer on a wall-mounted rack and let it air dry.

CAUTIONS

- The transducer steering mechanism is not sealed. If disinfectant or other fluid enters the steering mechanism, it will corrode the gears and electrical connections. Avoidable transducer damage is not covered by the warranty or service contract.
- Never sterilize the transducer with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

Sterilizing Transducers

Sterilization is required if the device is classified as a critical device and is used without a sterile cover, or if the sterile cover is breached.

WARNINGS

- Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.
- In neurosurgical applications, sterilized transducers should be used with a pyrogen-free transducer cover.
- If a premixed solution is used, be sure to observe the solution expiration date.

CAUTIONS

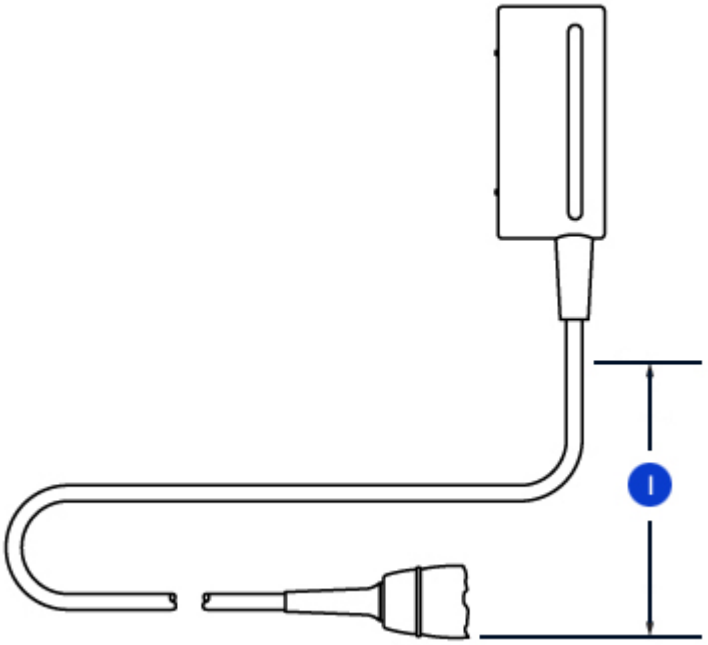
- Transducers must be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. Be sure to follow the manufacturer's instructions when using disinfectants.
- Use only liquid solutions to sterilized transducers. Using autoclave, gas (EtO), or other methods not approved by Philips Ultrasound will damage your transducer and void your warranty.
- Do not allow sharp objects, such as scalpels and cauterizing knives, to touch transducers or cables.
- When handling a transducer, do not bump the transducer on hard surfaces.
- Ensure the solution strength and duration of contact are appropriate for sterilization. Be sure to follow the manufacturer's instructions.

1. Clean the transducer according to "General Cleaning for All Transducers" on page 215.
2. Mix the sterilization solution compatible with your transducer according to label instructions for solution strength. A disinfectant listed in "Disinfectants Compatibility Table" on page 231 with the footnote "FDA 510(k) cleared" is recommended in the U.S.

3. Immerse the transducer in the sterilization solution as shown.
4. Follow the instructions on the sterilization label for the duration of transducer immersion required for sterilization.
5. Remove the transducer from the sterilization solution after the recommended sterilization time has elapsed.
6. Using the instructions on the sterilization label, rinse the transducer in sterile water up to the point of immersion, and then air dry or towel dry with a sterile cloth.
7. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer, and contact your Philips Ultrasound representative.

Immersing Transducers

1. Immerse this section only, up to 5.1 cm (2 in) from the connector's strain relief



Disinfectants Compatibility

Read this information before performing disinfection and sterilization procedures. It discusses recommended disinfectants and choosing an appropriate disinfectant for the required level of disinfection. You must check "Disinfectants Compatibility Table" on page 231 for the chemical compatibility of disinfectants and cleaners with specific transducers. In addition, the table indicates if a device can be sprayed or wiped only, or if it can be soaked.

WARNINGS

- Not all disinfectants are effective against all types of contamination. Ensure the disinfectant type is appropriate for the type of transducer and that the solution strength and time of contact are appropriate for the intended clinical use.
- Disinfectants listed in this section are recommended because of their chemical compatibility with product materials, not their biological effectiveness. For the biological effectiveness of a disinfectant, see the guidelines and recommendations of the disinfectant manufacturer, the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.
- If a premixed solution is used, be sure to observe the solution expiration date.
- Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTION

Using a non-recommended disinfection solution, using an incorrect solution strength, or immersing a transducer deeper or longer than recommended can damage the device and voids the warranty.

Disinfectant Types

WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the disinfectant type is appropriate for the type of transducer and the transducer application. For information on the levels of disinfection requirements, see "Choosing a Disinfectant" on page 214. For more information, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control, the U.S. Food and Drug Administration, and the U.S. Centers for Disease Control.

CAUTION

If you use an isopropyl alcohol solution for disinfection, ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage. Do not use alcohol on the transducer's strain relief or cable, or on TEE transducers (except the handle).

See "Disinfectants Compatibility Table" on page 231 for standard industry recommendations on disinfection, for information that can help you choose an appropriate disinfectant for the required level of disinfection, and for transducer-specific instructions.

Factors Affecting Disinfectant Efficiency

The following factors will affect the efficiency of a disinfectant solution:

- Duration of exposure
- Age of the solution
- Concentration and potency of the disinfectant
- Quantity and location of the contamination
- Resistance of the contaminate
- Organic matter on the item to be disinfected

Disinfectants Compatibility Table

The table that follows lists the disinfectants compatible with the transducers available for your system.

Other low- and intermediate-level disinfectants marketed for use on medical instruments and based on quaternary ammonium compounds (QUATS) or sodium hypochlorite (NaOCl), equal to or less than 0.6%, are approved for use.

NOTE

A 10% bleach solution typically provides a solution that is less than 0.6% NaOCl.

Additionally, products that contain 70% or less isopropyl alcohol (IPA) are acceptable for use on the transducer portion of the device only. (Do not use alcohol-based products on transducer cables and strain reliefs.)

Those disinfectant types must be used only in a spray or wipe application.

CAUTION

The preceding recommendations do not apply to TEE transducers.

For more information:

- Philips Ultrasound Transducer Care Web site (http://www.medical.philips.com/main/products/ultrasound/transducers/transducercare/)
- In North America, call Philips Ultrasound Customer Service at 800-722-9377.
- Outside North America, contact your local Philips Ultrasound representative.

Disinfectants Compatibility

Solution	Origin	Qualified Use	Active Ingredients	D2cwc	S5-1	X7-2t
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	T	T	H
AbcoCide	US	Soak[2]	Glutaraldehyde	N	T,C	T
AbcoCide 28	US	Soak[2]	Glutaraldehyde	N	T,C	T
Aidal	AU	Soak[2]	Glutaraldehyde	N	T,C	T
Aidal Plus	AU	Soak[2]	Glutaraldehyde	N	T,C	T
Alkaspray	FR	Spray/Wipe	Alcohol, Alkylamine	T	T	N
Ampholysine Basique	FR	Spray/Wipe	Biguanide/Quat. Ammonia	T,C	T,C	C
Banicide	US	Soak[2]	Glutaraldehyde	N	T,C	C
Bleach (10% solution of 5.25% Bleach)	All	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	T
CaviWipes	US	Wipe	Alcohol, Quat. Ammonia	T	T	N
Cidex[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
Cidex 7[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
Cidex OPA[1]	US	Soak[2]	Ortho-phthalaldehyde	N	T,C	T
Cidex PAE 14J	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Cidex Plus[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
Descoton Extra	DE	Soak[2]	Glutaraldehyde	N	T,C	T
Dispatch	US	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	C
Endo FC	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Endosporine	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Enzol	US	Pre-cleaner	Enzymes	N	T,C	T
Epizyme Rapid	AU	Pre-cleaner	Enzymes	N	T,C	T
Gigasept FF	DE	Soak[2]	Succindialdehyde, dimethoxy tetrahydrofuran	N	N	N
Incidin	DE	Spray/Wipe	Alcohol	T	T	H

Solution	Origin	Qualified Use	Active Ingredients	D2cwc	S5-1	X7-2t
Incidur Spray	DE	Spray/Wipe	Alcohol, Quat. Aldehyde	T	T	N
Instruzyme	FR	Pre-cleaner	Enzymes, Quat. Ammonia, Biguanide	N	N	T
Klenzyme	US	Pre-cleaner	Enzymes	N	T,C	T
Kohrsolin	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Korsolex PAE	FR	Soak[2]	Glutaraldehyde	N	T,C	T
MaxiCide Plus	US	Soak[2]	Glutaraldehyde	N	T,C	T
MetriCide[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
MetriCide 28[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
MetriCide OPA Plus[1]	US	Soak[2]	Ortho-phthalaldehyde	N	T,C	T
MetriCide Plus 30[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
Metrizyme	US	Pre-cleaner	Enzymes	N	T,C	T
Mild Soap Solution	All	Pre-cleaner	Surfactants/Soap	T,C	T,C	T,C,H
Milton	AU	Spray/Wipe	Sodium Hypochlorite	T,C	T,C	C
Omnicide 14NS	US	Soak[2]	Glutaraldehyde	N	T,C	T
Omnicide 28	US	Soak[2]	Glutaraldehyde	N	T,C	T
Opticide3	US	Spray/Wipe	Alcohol, Quat. Ammonia	T	T	N
PeraSafe Powder	UK	Soak[2]	Peracetic	N	N	T
Perascope	UK	Soak[2]	Peracetic	N	N	T
Phagocide D	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Phagozyme ND	FR	Pre-cleaner	Enzymes, Quat. Ammonium	N	N	T
Pro-Cide	US	Soak[2]	Glutaraldehyde	N	T,C	T
Pro-Cide 14NS[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T
Pro-Cide 28	US	Soak[2]	Glutaraldehyde	N	T,C	T
Pro-Cide NS	US	Soak[2]	Glutaraldehyde	N	T,C	T
Pro-Cide Plus	US	Soak[2]	Glutaraldehyde	N	T,C	T

Solution	Origin	Qualified Use	Active Ingredients	D2cwc	S5-1	X7-2t
PSS Select 14 Day	US	Soak[2]	Glutaraldehyde	N	T,C	T
PSS Select 28 Day	US	Soak[2]	Glutaraldehyde	N	T,C	T
PSS Select Plus	US	Soak[2]	Glutaraldehyde	N	T,C	T
Quaternary Ammonium	All	Spray/Wipe	Quat. Ammonia	T,C	T,C	C
Rivascop	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	C
Salvanios pH 10	FR	Spray/Wipe	Quat. Ammonia	T,C	T,C	C
Sanicloth HB	US	Wipe	Quat. Ammonia	T,C	T,C	C
Sanicloth Plus	US	Wipe	Alcohol, Quat. Ammonia	T	T	N
SDS 14 NS	US	Soak[2]	Glutaraldehyde	N	T,C	T
SDS 28	US	Soak[2]	Glutaraldehyde	N	T,C	T
Sekucid N	FR	Soak[2]	Glutaraldehyde	N	T,C	T
Sekusept Aktiv	DE	Soak[2]	Peracetic	N	N	T
Sekusept Easy	DE	Soak[2]	Peracetic	N	N	T
Sekusept Plus	DE	Soak[2]	Glucoprotamin	N	N	N
Steranios 2%	FR	Soak[2]	Glutaraldehyde	N	T,C	T
TD-5	US	TD-100 Reprocessor	Glutaraldehyde	N	N	T
T-Spray	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	C
T-Spray II	US	Spray/Wipe	Quat. Ammonia	T,C	T,C	H,C
Vaposeptol	FR	Spray/Wipe	Alcohol, Biguanide	T	T	H
Vespore	US	Soak[2]	Glutaraldehyde	N	T,C	T
Wavicide -01[1]	US	Soak[2]	Glutaraldehyde	N	T,C	T

C = Approved for use on the cable

N = Not approved for use

T = Approved for use on the transducer

H =Approved for use on the handle (TEE transducers only)

1. FDA 510(k) cleared

2. Soak or per product instructions

AU = Australia

DE = Germany

FR = France

UK = United Kingdom

US = United States

Gels Compatibility

Although most gels will provide suitable acoustic coupling, some gels are incompatible with certain transducer materials. Products that do not contain mineral oil are acceptable for use. Never use lotion-based products.

WARNING

For intraoperative applications, use only the Sterile Aquasonic or Sterile Ultraphonic gel provided with the transducer cover.

CAUTIONS

- Do not use gels that contain mineral oil or lotion. Such products may damage the transducer and void the warranty.
- Gels listed in this section are recommended because of their chemical compatibility with product materials.

Some recommended gels include:

- Aquasonic 100
- Aquasonic Clear
- Carbogel-ULT
- ECG Gel (Nicom)
- Nemidon Gel
- Scan

For additional compatibility information, call Philips Ultrasound Customer Service at 800-722-9377 (North America) or your local Philips Ultrasound representative (outside North America).

11 System Maintenance

Maintenance should be performed regularly and as needed.

Cleaning and Maintaining the System

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is particularly important for pieces of peripheral equipment because they contain electromechanical devices. If exposed to constant and excessive environmental dust and humidity, these devices will suffer in both performance and reliability.

NOTE

At a certain internal system temperature, the system displays a warning message and then turns off automatically 30 minutes later. Increased internal temperature can result from obstructed vents on the front and back of the system. Failure to keep the vents clean can result in the system becoming unavailable during critical use.

It is essential to clean the transducers used with your ultrasound system. The cleaning procedures vary for the different types of transducers and their uses.

For detailed instructions on how to clean and maintain each type of transducer used with the system, including disinfectant compatibility, see the "Transducer Care" section.

Cleaning the System and ECG Equipment

Use this method to clean the system, the optional cart, and the ECG cables, leads, and electrodes. You can use a mild soap solution. If the equipment has come in contact with blood or infectious material, clean the equipment with a 70% solution of isopropyl alcohol. For instructions on disinfecting system surfaces, see "Disinfecting System Surfaces" on page 239.

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTIONS

- Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and voids the warranty.
- Orient the parts that must remain dry higher than the wet parts until all parts are dry.
- Remove the battery from the system before performing any cleaning (see "Installing the Battery" on page 131). If necessary, clean the battery separately (see "Cleaning the Battery" on page 241).

Use the following procedure to clean the display; the system control panel; and all the external surfaces of the system and the optional cart; the ECG trunk cables, leads, and electrodes.

1. Before cleaning, turn off the system and unplug the power cord from the power source.
2. Wipe with a soft cloth moistened with soap and water.

CAUTIONS

- Do not spill or spray liquid on the controls, into the system cabinet, or into the transducer connection receptacle.
- Do not spill or spray liquid on the AC tray at the bottom of the optional cart.

3. Remove any solid matter around the keys or the controls with a cotton swab or toothpick to ensure that solids are not pushed into the cabinet.
4. If blood or other infectious material comes in contact with the system or any cable other than a transducer cable, wipe with a 70% solution of isopropyl alcohol.

CAUTION

If blood or other infectious material comes in contact with a transducer or transducer cable, do not wipe with isopropyl alcohol until you have read the "Transducer Care" section for specific cleaning guidelines. Isopropyl alcohol should not be used on some parts of the transducer and should never be used on any parts of the transducer cable. Additional cleaning agents are also available for transducers.

5. Remove any residue with a cloth moistened with sterile water.
6. Be sure to dry the equipment to prevent potential corrosion.

Disinfectants for System Surfaces

The exterior surfaces of the system can be disinfected using a compatible disinfectant with a wipe method. System surfaces include the monitor screen and plastic and painted surfaces. The following products can be used on system surfaces:

- Mild soap solution
- 70% isopropyl alcohol (IPA)
- T-Spray II (quaternary ammonium-based)
- Opti-Cide-3 (quaternary ammonium/isopropyl alcohol-based)
- Sani-Cloth HB (quaternary ammonium-based)
- Sani-Cloth Plus (quaternary ammonium/isopropyl alcohol-based)

Other products that are based on quaternary ammonium compounds (QUAT) or QUAT/isopropyl alcohol can also be used in disinfecting system surfaces.

Disinfecting System Surfaces

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTIONS

- Use only compatible disinfectants on system surfaces.
- If you use an isopropyl alcohol solution for disinfection, ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.

Before performing this procedure, read "Disinfectants for System Surfaces" on page 239.

1. Turn off the system and disconnect the system power cord from the wall outlet.
2. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean exterior surfaces on the system.
3. Mix the disinfection solution compatible with your system according to label instructions for solution strength.

CAUTION

Do not spray disinfectant directly on system surfaces. When wiping, do not allow disinfectant to pool or run on system surfaces. In either case, disinfectant may leak into the system, damaging the system and voiding the warranty. Wipe only with a cloth or applicator that is lightly dampened.

4. Wipe system surfaces with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and disinfectant contact duration. Ensure the solution strength and duration of contact are appropriate for the intended clinical application.
5. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.

Because the system is a piece of medical equipment that contains several circuit boards, extensive service diagnostics, and complex operating software, Philips recommends that only trained personnel service the system.

Cleaning the Trackball

Cleaning the trackball regularly prolongs its useful life and prevents service calls.

1. Unscrew the ring around the trackball. A paper clip inserted into one of the small holes in the ring can help to start unscrewing the ring.
2. Lift the trackball out of the mounting area.
3. Clean the trackball and the mounting area with a lint-free cloth or a small brush.
4. Place the ball back on the mounting area.
5. With your fingers, screw the ring back on.

Cleaning the Battery

Use this method to clean the system battery.

WARNINGS

- Do not immerse the battery.
- Keep moisture and liquid away from the battery connector.

CAUTION

Do not spill or spray liquid on the battery.

1. Before cleaning the battery, remove it from the system (see "Installing the Battery" on page 131).
2. Wipe the battery with a dry cloth. If spot cleaning is necessary, wipe with a cloth dampened with soap and water (avoid the connector area). If disinfection is necessary, wipe with an alcohol-moistened towelette or cloth.
3. Remove any solid matter with a cotton swab or toothpick to ensure that solids are not pushed into the battery.
4. Let the battery dry thoroughly before installing it in the system.

Cleaning the Adapter

Use this method to clean the adapter.

WARNINGS

- Do not immerse the adapter.
- Keep moisture and liquid away from the adapter. Do not spill or spray liquid on the adapter.

1. Before cleaning the adapter, disconnect it from the system and the wall outlet.
2. Wipe the adapter with a dry cloth. If spot cleaning is necessary, wipe with a cloth dampened with soap and water. If disinfection is necessary, wipe with an alcohol-moistened towelette or cloth.
3. Remove any solid matter with a cotton swab or toothpick to ensure that solids are not pushed into the adapter.
4. Let the adapter dry thoroughly before plugging it into the system or wall outlet.

Transducer Maintenance

For all information on transducer cleaning and disinfection and the use of acoustic coupling gels, see the "Transducer Care" section.

Printer Maintenance

WARNING

Before performing any maintenance on a device, always disconnect it from the source of power by either of the following: Disconnect the system from the wall outlet, if the device is internal to the system; or disconnect the device from the wall outlet, if it is external to the system.

CAUTIONS

- Do not scratch the roller or allow dirt and dust to contact the roller of a printer.
- Do not use strong solvents such as thinner or benzine, or abrasive cleaners, because those will damage a device cabinet.

Periodically clean the external surfaces of a device with a soft cloth. Difficult stains may be removed with a cloth lightly dampened with a mild detergent solution.

Troubleshooting

If you encounter difficulty in the operation of the system, use the information here to help correct the problem. If the problem is not covered here, contact your Philips Ultrasound customer support representative.

The troubleshooting table contains a list of symptoms and the actions to take to correct the problems.

Troubleshooting

Symptoms	Corrective Action
The system does not power up. The monitor indicator light is off.	1. Verify the power connections. 2. Check the circuit breaker on the optional cart.
No image displays on the monitor.	1. After power up, the system takes about 20 seconds to initialize. During this time the monitor is blank. 2. After 20 seconds, adjust the **Monitor** brightness in **System** setups. 3. Check the monitor cables and connections.
No audio comes from the system speakers.	Use the **Volume** control to ensure the speakers are not muted.
An error message is displayed.	Note the error message and contact your Philips Ultrasound customer support representative.
An error message indicates that the system is above normal operating temperature.	1. Click **Continue**. The system will power down automatically in 30 minutes. 2. With power off, clean the vents on the front and back of the system (see "Cleaning the System and ECG Equipment" on page 237).

Error Messages

The system displays error messages in response to operating or error conditions detected by the system.

The error messages must be noted and reported to your Philips Ultrasound customer support representative.

Do not use the system if an error message is displayed.

For Assistance

If you are unable to correct a problem, call your local Philips Ultrasound customer support representative.

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